

THE NEGATIVE IMPACT OF INTELLECTUAL PROPERTY PATENT RIGHTS ON DEVELOPING COUNTRIES: AN EXAMINATION OF THE INDIAN PHARMACEUTICAL INDUSTRY

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I. INTRODUCTION

*The post-colonial world has retained forms of manipulation, exploitation, and cultural expropriation, even if colonialism itself belongs to the past.*¹

Prior to World War II, the world order was divided between states that were colonized and their colonizers.² At the end of the war, most colonies acquired independence.³ However, due to the mass exploitation of their resources and people during those years, the post war development

1. JURGEN OSTERHAMMEL, *COLONIALISM: A THEORETICAL OVERVIEW* (Shelley L. Frisch trans., Markus Wiener Publishers 1997) 119 (1995) (emphasis added).

2. See THOMAS SOWELL, *CONQUESTS AND CULTURES: AN INTERNATIONAL HISTORY* 82 (1998). Major European powers, including Britain, Spain and France converted parts of the less developed world "creating a uniquely European age of overseas imperialism, spanning the globe." *Id.* See OSTERHAMMEL, *supra* note 1, at 6-7. The colonies were sometimes established in sparsely inhabited lands lacking highly integrated native states such as North America and Africa. See *id.* However, colonies were also established in lands where states and civilizations had existed since ancient times, such as in India. See *id.* at 8. Additionally, the emigration of "white" colonists often carried an attitude of presumed superiority over the native populations. See *id.* at 11. Often termed by the European powers as "The White Man's Burden," there existed a notion that the developed nations have a duty to rule Africans, Asians and Aboriginal peoples in order to lead them to a higher level of culture and civilization. See *id.* at 16. See also William G. Clarence-Smith, *The Modern Colonial State and Global Economic Integration, 1815-1945*, in *STATES AND SOVEREIGNTY IN THE GLOBAL ECONOMY* 120, 129 (David A. Smith et al. eds., 1999) (noting the danger to the non-white colonies caused by the spread of social Darwinism).

3. The decolonization of Asia, Africa, the Caribbean and South America began through a post World War II transfer of power, when the Western European colonizing countries' economies, including the economies of Britain, France, Spain, Portugal and Holland, were extremely depleted due to the war. See OSTERHAMMEL, *supra* note 1, at 115. Additionally, anti-imperialist feelings sparked the development of national liberation movements within many colonized countries. See *id.* at 116. See also D.K. FIELDHOUSE, *THE WEST AND THE THIRD WORLD* 19 (1999) (identifying that decolonization began after 1945). Cf. SOWELL, *supra* note 2, at 84, 337 (pointing to the fact that in the post World War II era many Western imperial nations withdrew from their colonies).

of these former colonies was severely impeded.⁴ Today, many of these former colonies comprise those states referred to as developing countries, while their colonizers are considered the developed or industrialized nations.⁵ Although developing countries have acquired statehood, they re-

4. See SOWELL, *supra* note 2, at 82. European colonizing countries established trading empires in many countries, which they colonized for the purposes of exploiting the minerals and resources of those countries. *See id.* While European imperialism did bring a form of economic expansion to the colonized countries, it also brought brutal exploitation and dehumanization at the hands of alien cultures, which held themselves out as being superior to the native populations. *See id.* at 82-83. *See also* FIELDHOUSE, *supra* note 3, at 3 (describing the motives of colonizing nations, as selfish and for the purpose of acquiring minerals and crops); OSTERHAMMEL, *supra* note 1, at 7, 72 (acknowledging that the colonization of a nation often had a parasitic effect on the dominated economy to the benefit of the colonizer, through the acquisition of natural resources and human labor). *Cf.* Lakshmi Sarma, Note & Comment, *Biopiracy: Twentieth Century Imperialism in the Form of International Agreements*, 13 TEMP. INT'L & COMP. L.J. 107, 109-10 (1999) (pointing to the fact that the some countries remain underdeveloped because of the remnants of colonialism).

5. See SOWELL, *supra* note 2, at 83. Because of its particular suitability to settlement and exploitation, the colonies of North America, Australia and New Zealand tended to be more permanent in nature as they established new settlements with transplanted members of the colonizing state. *See id.* In addition, North America, like Australia, experienced the Industrial Revolution at relatively the same time as the colonizing nations. *See id.* at 67. *See also* Clarence-Smith, *supra* note 2, at 120-21 (establishing that colonies such as Canada, Australia, and New Zealand were known as Britain's "White Dominions"); FIELDHOUSE, *supra* note 3, at 19 (referring to the colonies of white settlement, Canada, Australia and New Zealand as British Dominions, while most other colonies were viewed as dependencies); OSTERHAMMEL, *supra* note 1, at 7 (illustrating that North America, Australia and New Zealand were colonized for permanent settlement purposes). *Cf.* Evelyn Su, Comment, *The Winners and the Losers: The Agreement on Trade-Related Aspects of Intellectual Property Rights and its Effects on Developing Countries*, 23 HOUS. J. INT'L L. 169, 170 n.1 (2000) (developing countries are countries whose economies are less advanced than industrialized nations (citing PAUL R. KRUGMAN & MAURICE OBSTFELD, *INTERNATIONAL ECONOMICS: THEORY AND POLICY* 240 (2d ed. 1991))). *See, e.g.,* WTOWATCH.org, *Fast Fact: The World Trade Organization* (listing the developing countries as designated by the WTO), at <http://www.wtowatch.org/faq/faq.cfm> (last visited Feb. 26, 2001) (on file with author). Terms that refer to the 'West' and the 'Third World' are terms of art, rather than exact definitions. *See generally* FIELDHOUSE, *supra* note 3, at 1. Synonyms for the West can include 'industrialized economies' or the 'North' and most often refer to relatively rich countries, or affluent industrialized states. *Id.* The Third World, is viewed by some, as the 'Rest,' and in general discourse indicates Latin American, African and Asian countries, those that are economically less developed than the 'West.' *See id.* at 2. This grouping of countries has been alternately referred to as the 'South,' 'less-developed countries' (LDCs) or developing countries. *See id.* at 2-3. Throughout this paper the terms referring to developing and developed countries will be varied. Developed countries may be referred to as industrialized nations, the north or the west, while developing countries are referred to as industrializing nations, less-developed countries, third world countries or the south.

main subject to the demands and control of the industrialized countries in order to survive in the increasingly global world order.⁶

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs),⁷ provides one example of such continued economic and political dominance by industrialized nations. TRIPs was introduced in December 1993, during the Uruguay Round of the General Agreement of Tariffs and Trade (GATT),⁸ in order to set minimal international standards for the protection of intellectual property.⁹ However, developed

6. Many post-colonization nations entered into a patron-client position of dependence, often on the United States. See OSTERHAMMEL, *supra* note 1, at 116. This new form of dependence could be attributed to the fact that despite the acquisition of sovereignty, most new states were economically unprepared. See *id.* at 117. The new states were caught between a choice of self-isolation or a "humble acceptance of peripheral market opportunities" such as multinational concerns and international economic organizations. *Id.* Thus "[d]ecolonization gave the ex-colonies freedom of action, but seldom the opportunity to exploit it to full advantage." *Id.* Former colonies remain subject to a new form of economic domination based on the economic superiority of stronger national partners, see *id.* at 21, such as the United States. The stronger partner maintains dominance due to its ability to affect multinational concerns, and provide protective military functions, thereby influencing the politics of the weaker former colonized nations. See *id.* Today, many developing countries assert that their economic development is still in the hands of the developed countries and has been seriously impacted by unfair trading practices and a lack of control over international business corporations. See *id.* See also Su, *supra* note 5, at 195 (stating that an underlying characteristic of developing countries is that they must play catch-up with the advanced industrialized countries); Wendy S. Vicente, Comment, *A Questionable Victory for Coerced Argentine Pharmaceutical Patent Legislation*, 19 U. PA. J. INT'L ECON. L. 1101, 1130-31 (1998) (remarking that developing nations are relegated to dependency upon developed nations). See generally SOWELL, *supra* note 2, at 330 (noting that widespread belief exists that "the rich are rich because the poor are poor").

7. Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 1197 (1994) [hereinafter TRIPs Agreement]. See also *Implications of Uruguay Round Patent Moves*, MARKETLETTTER, May 30, 1994, available at 1194 WL 2620598 [hereinafter *Implications of Uruguay Round*].

8. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 1 (1994), 33 I.L.M. 1125 (1994) [hereinafter Final Act]. GATT was formally signed on April 15, 1994, in Marrakesh Morocco, by representatives from 124 member countries. *Id.* at 1131-32. The trade pact opens global markets between member countries for goods and services and projects a worldwide reduction of tariffs and an increase in annual global income. *Id.* at 1127. The Treaty established a successor to GATT, the World Trade Organization (WTO), which replaced GATT on January 1, 1995. *Id.*

9. See TRIPs Agreement, *supra* note 7. See also Margreth Barrett, *The United States' Doctrine of Exhaustion: Parallel Imports of Patented Goods*, 27 N. KY. L. REV. 911, 918 n.22 (2000) (noting that the Uruguay Round of Negotiations on the GATT introduced minimum standards for protection of intellectual property rights); Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPs Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L.

and developing countries differ in approach on how to address intellectual property rights.¹⁰ In particular, developing countries have strong incentives to under enforce intellectual property laws, while developed countries reap many benefits from strict enforcement.¹¹ For developing countries, signing onto TRIPs was a compromise in exchange for acquiring GATT tariff concessions on goods.¹² Specifically, under the Uruguay Round, the developed countries extracted promises of intellectual property protection from the developing countries in exchange for lower tariffs on their export goods.¹³

India is a prominent example of a developing country that has resisted strong protection of intellectual property rights.¹⁴ India, like many devel-

41, 62 (1998) (explaining that TRIPs established minimum standards of intellectual property but that a country could implement more extensive protection if desired).

10. McCabe, *supra* note 9, at 52-53. See Tuan N. Samahon, Note, *TRIPs Copyright Dispute Settlement after the Transition and Moratorium: Nonviolation and Situation Complaints Against Developing Countries*, 31 LAW & POL'Y INT'L BUS. 1051, 1055 (2000). Prior to the introduction of TRIPs, the World Intellectual Property Organization (WIPO) was the forum of choice for developing countries to discuss intellectual property issues. See *id.* Unlike TRIPs, which is included within the WTO system, WIPO focused only on intellectual property rights and did not have a sanctioning method; thus, WIPO provided developing countries a greater latitude in enforcing obligations relating to intellectual property. See *id.* Under the WTO system, intellectual property rights are protected by enforcement mechanisms and a Dispute Settlement Body [DSB]. See *id.* at 1057. See also Robert Weissman, *A Long Strange TRIPs: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1085 (1996) (noting that third world countries favored WIPO negotiations to revise intellectual property obligations over their inclusion in the GATT).

11. See McCabe, *supra* note 9, at 53 (intimating that developing countries view strong intellectual property protection as only benefiting industrialized countries that export intellectual property).

12. See Robert M. Sherwood, *The TRIPs Agreement: Implications for Developing Countries*, 37 IDEA 491, 494 (1997). Sherwood asserts that because the TRIPs Agreement was the product of multilateral negotiations, the Agreement represents a compromise between countries' with strongly divergent views regarding the benefit of intellectual property for development. *Id.* See also Gerald J. Mossinghoff, *National Obligations Under Intellectual Property Treaties: The Beginning of a True International Regime*, 9 FED. CIR. B.J. 591, 598 (2000) (discussing the use of linkage-bargain diplomacy in order to secure the developing countries' acceptance of intellectual property protection within the GATT negotiations); Samahon, *supra* note 10, at 1055 (stating that for developing countries, "accession to the WTO represented a Faustian bargain: In exchange for present GATT tariff concessions on goods, developing countries agreed to adequately protect intellectual property in the future").

13. See Mossinghoff, *supra* note 12, at 598; Samahon, *supra* note 10, at 1055.

14. See Doris E. Long & Anthony D'Amato, *Introduction: A Trip Begins*, in INTERNATIONAL INTELLECTUAL PROPERTY 7 (Doris Long & Anthony D'Amato eds., 2000) [hereinafter Long & D'Amato, *Introduction: A Trip Begins*]; Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provisions in the TRIPS Agreement: The Case of India*,

oping countries and humanitarian organizations, has vehemently protested patent protection for pharmaceuticals.¹⁵ Currently, pharmaceutical product patents in India are not held to the highest standards of intellectual property patent protection and are often freely copied.¹⁶ Without highly enforced patents, drugs can be offered at significantly lower prices.¹⁷ Thus, India's resistance to the implementation of stringent patent laws for pharmaceuticals has been motivated by a belief that alleviating the country's health problems should take priority over foreign corporations' rights to derive profits by maintaining a monopoly on a particular invention.¹⁸

India's commitment to improving the health of its people is shared by many developing countries and is recognized as a priority by the World

29 VAND. J. TRANSNAT'L L. 507 (1996); David K. Tomar, Note & Comment, *A Look into the WTO Pharmaceutical Patent Dispute Between the United States and India*, 17 WIS. INT'L L.J. 579, 579 (1999). See also Anthony D'Amato & Doris E. Long, *Asia and the Protection of Intellectual Property*, in INTERNATIONAL INTELLECTUAL PROPERTY LAW 296 (Anthony D'Amato & Doris Long eds., 1997) [hereinafter D'Amato & Long, *Asia and the Protection of Intellectual Property*] (explaining that many Indians regard the imposition of intellectual property as economic colonialism). Cf. Robert Evans, *WTO Chief to Visit India on Trade Round Effort* (Jan. 5, 2000) (stating that India, which is arguably one of the world's most influential trading states, is widely seen as a major player in determining the position of developing countries on trade issues), at <http://www.wtowatch.org/news/index.cfm> (last visited May 15, 2001) (on file with author).

15. See Long & D'Amato, *Introduction: A Trip Begins*, *supra* note 14, at 7; Adelman & Baldia, *supra* note 14, at 525-27. One well recognized humanitarian organization, Médecins Sans Frontiers, or Doctors Without Borders, has undertaken a campaign to ensure access to essential medicines, particularly for the most common global infectious diseases found predominately in developing countries. See Médecins Sans Frontiers, *Campaign of Access to Essential Medicines*, at <http://www.msf.org/advocacy/accessmed/> (last visited Feb. 26, 2001) (on file with author).

16. See David Hurlbutt, *Fixing the Biodiversity Convention: Toward a Special Protocol for Related Intellectual Property*, 34 NAT. RESOURCES J. 379 (1994), excerpt reprinted in INTERNATIONAL INTELLECTUAL PROPERTY LAW 37 (Anthony D'Amato & Doris Long eds., 1997). See generally Adelman & Baldia, *supra* note 14, at 507 (condemning the Indian pharmaceutical industry for 'free-rid[ing]' on the intellectual property developments of other countries).

17. See Hurlbutt, *supra* note 16, at 37 (noting that drugs are available in India for as little as seven to twenty percent of the cost of comparable drugs in the United States).

18. See Long & D'Amato, *Introduction: A Trip Begins*, *supra* note 14, at 7 (commenting on the Indian position that patent protection for essential pharmaceuticals would place them beyond the reach of the Indian people); Hurlbutt, *supra* note 16, at 37 (relating the idea that a patent creates a monopoly by the person holding the patent by preventing anyone else from duplicating and selling it at a lower rate). See also Immanuel Wallerstein, *States? Sovereignty? The Dilemmas of Capitalists in an Age of Transition*, in STATES AND SOVEREIGNTY IN THE GLOBAL ECONOMY 20, 25 (David A. Smith et al. eds., 1999) (condemning the fact that while many free market states forbid monopolies, it appears that "[b]y re-labeling such monopolies 'intellectual property,' the hope is that no one will notice how incompatible this notion is with the concept of a free market").

Health Organization (WHO).¹⁹ Additionally, in the 1948 adoption of the Universal Declaration of Human Rights, the United Nations recognized that all people have a right to adequate health and well being, including medical care.²⁰ Unfortunately, despite a recognized commitment to healthcare, a significant aspect of the economic gap between developed and developing countries is evidenced by the large disparity between health conditions in rich and poor countries.²¹ This is especially daunting considering that the process of globalization appears to be increasing, rather than narrowing the health gap.²²

19. Constitution of the World Health Organization, preamble, *opened for signature* July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185 (providing that enjoyment of the highest attainable standard of health is a fundamental human right of every human being). See WORLD HEALTH ORGANIZATION, THE WORLD HEALTH REPORT 1999: MAKING A DIFFERENCE 13 (1999) [hereinafter WORLD HEALTH REPORT 1999] (noting that reducing the burden of inequality in health is a priority in international health). See also David P. Fidler, *Neither Science Nor Shamans: Globalization of Markets and Health in the Developing World*, 7 IND. J. GLOBAL LEGAL STUD. 191, 191 (1999).

20. UNIVERSAL DECLARATION OF HUMAN RIGHTS, art. 25(1). Article 25 states "[E]veryone has the right to a standard of living adequate for health and well-being of himself and of his family, including food . . . and medical care . . . and the right to security in the event of unemployment, sickness, disability . . ." *Id.*

21. See WORLD HEALTH REPORT 1999, *supra* note 19, at 20, 22 (noting that in developing countries infectious diseases are the major cause of premature death). See also Fidler, *supra* note 19, at 191, 194. Fidler argues that this economic gap is of particular concern as populations in developing countries face continued threats from infectious diseases in addition to growing epidemics of non-communicable diseases. See *id.* While industrialized countries have had tremendous breakthroughs in handling infectious diseases through effective vaccines and antibiotics, developing regions have not experienced the same health transition. *Id.* The infectious disease problem in developing countries is worsening, as indicated by the dramatic spread of HIV/AIDS, the development of anti-microbial resistance to malaria, pneumonia, tuberculosis, and the continued illness and death brought on by water borne diseases such as cholera. *Id.* at 195. UNAIDS estimates that over 95% of all persons infected with HIV live in the developing world. See *id.* at 195 n.13 (citing UNAIDS, *AIDS Epidemic Update*, Dec. 1998, at 2 (1998)).

22. World Health Assembly, *Strengthening Health Systems in Developing Countries*, WHA 52.23, May 25, 1999 [hereinafter WHA 52.23, *Strengthening Health*], available at http://www.who.int/wha-1998/WHA99/PDF99/e_reso.pdf. (on file with author). In this report the WHO stated it was:

[m]indful of the fact that globalization presents opportunities and challenges for all countries and that developing countries, especially the poorest, are vulnerable to those adverse effects of globalization which lead to greater inequities in health and health care both within such countries and between developed and developing countries.

Id. See also Médecins Sans Frontières, *Report to the National AIDS Committee of Thailand*, (Aug. 1999) [hereinafter Médecins Sans Frontières, *Report to Thailand*] (noting that developing countries are merely passive recipients of the effects of globalization rather than its beneficiaries), available at <http://www.accessmed-msf.org> (on file with author). See Fidler, *supra* note 19, for a detailed discussion of the health-globalization relationship. The process of globalization is broad and encompasses increased international business corpo-

The Indian population exceeds one billion people.²³ The majority of this population lives below the poverty line.²⁴ Due to this mass poverty, a primary concern for the Indian government is that patent protection would result in an inevitable increase in the price of medicine.²⁵ Such price increases would make prescription drugs unaffordable and therefore unavailable to those who are most in need.²⁶ If the majority of the population is unable to gain access to essential medicines because of price increases caused by stringent patent protection, the fear that millions of people could die becomes more of a reality.

It is evident that the TRIPs Agreement, in its current form, acts as a vehicle for Western imperialism over developing countries.²⁷ This imperialism was evidenced by the use of the GATT/WTO forum by developed countries to implement the TRIPs agreement, thereby imposing mandatory protection of intellectual property rights.²⁸ Additionally, this

rations as well as international legal structures such as the World Trade Organization. *See id.* at 192. Globalization is a process dominated by market influences, which have had a negative impact on public health in developing countries. *Id.* The focus of this paper will be the effect of TRIPs patent provisions on the health needs of developing countries, in the new globalized world order.

23. *See* Office of the Registrar General of India, Census of India, *Population Clock*, (stating that the population of India on March 1, 2001 was 1,012,395,934), available at <http://www.censusindia.net/pclock.html> (last visited March 24, 2001) (on file with author).

24. *See* Hurlbutt, *supra* note 16, at 37.

25. *Cf.* Suresh Koshy, Note, *The Effect of TRIPs on Indian Patent Law: A Pharmaceutical Industry Perspective*, 1 B.U. J. SCI. & TECH. L. 4, para. 1 (1995) (noting that India maintains weak patent laws to provide inexpensive products to its citizens).

26. *See* George K. Foster, Comment, *Opposing Forces in a Revolution in International Patent Protection: The U.S. and India in the Uruguay Round and Its Aftermath*, 3 UCLA J. INT'L L. & FOREIGN AFF. 283, 309 (1998).

27. *See* Marcia A. Hamilton, *The TRIPs Agreement: Imperialistic, Outdated, and Over-protective*, 29 VAND. J. TRANSNAT'L L. 613 (1996) (denouncing the TRIPs as "old-fashioned, Western-style imperialism"), excerpt reprinted in INTERNATIONAL INTELLECTUAL PROPERTY 361, 362 (Doris Long & Anthony D'Amato eds., 2000); Sarma, *supra* note 4, at 125 (dismissing the GATT/TRIPs agreement as simply a form of modern-day colonialism disregarding the differing needs of the lesser developed nations); Michael W. Smith, Note, *Bringing Developing Countries' Intellectual Property Laws to TRIPs Standards: Hurdles and Pitfalls Facing Vietnam's Efforts to Normalize an Intellectual Property Regime*, 31 CASE W. RES. J. INT'L L. 211, 227 (1999) (noting that there are many who view the TRIPs as a vehicle of Western imperialism). *See also* Roger Cohen, *The World Trade Agreement: The Overview; GATT Talks End in Joy and Relief*, N.Y. TIMES, Dec. 16, 1993, at D1 (indicating that many Indian legislators denounced the signing of the Agreement as the sale of the country to American Imperialists).

28. *See* Fidler, *supra* note 19, at 209. The developed countries were led by the United States. *Id.* In order for developing countries to receive the trade benefits available through membership in the WTO, the member states were required to accept the obligations of intellectual property through TRIPs. *See id.* *See also* Hamilton, *supra* note 27, at 362.

imperialism is also evidenced by the United States' unilateral action of sanctioning countries, which fail to provide the desired level of intellectual property protection. The provisions that would support developing countries are under-enforced, while those that benefit the industrialized developed countries are over-enforced.²⁹ Considering that there is no guaranteed access to essential drugs for one-third of the world's population, the opposition to the implementation of intellectual property protection of pharmaceutical patents must not be ignored.³⁰

This comment explores India's resistance to strong intellectual property protection in the area of pharmaceutical patents. This resistance reflects concerns felt by many developing countries.³¹ Section II begins with a brief overview of the nature of intellectual property as it relates to patents, and examines the diverging views held by developing and industrialized nations. Section III reviews the Uruguay Round of GATT and the implementation of TRIPs. This section also compares the competing perspectives of the industrialized and developing nations, about TRIPs, as evidenced by the current positions of the United States and India, respectively. An analysis of the WTO dispute resolution mechanism will also be undertaken.

Section IV presents a brief review of the history and current state of India's patent regime. Section V presents the cases for and against a strong intellectual property regime for pharmaceutical patents in developing countries, such as India. Section V also includes an overview of the

29. See Médecins Sans Frontières, *Report to Thailand*, *supra* note 22 (noting that several developing countries have been pressured by Western governments to change trade laws that would restrict their ability to produce or import drugs).

30. World Health Assembly. *Revised Drug Strategy*, WHA 52.19, May 24, 1999 [hereinafter WHA 52.19, *Revised Drug Strategy*], available at http://www.who.int/wha-1998/WHA99/PDF99/e_reso.pdf. (on file with author). In her first major policy speech, the Director-General stated that never before have so many been denied access to health. See Press Release, World Health Organization, Director-General Sets out WHO Stance on Health and Human Rights (Dec. 8, 1998) (on file with author). She also noted that the developing countries carry ninety percent of the disease burden, but only have access to ten percent of health resources. *Id.* See also Press Release, World Health Organization, WTO to Address Trade and Pharmaceuticals (May 22, 1999) (on file with author) (acknowledging that in the most impoverished parts of Asia and Africa the proportion of the population which is deprived access to essential drugs rises from one-third to one-half). See generally Fidler, *supra* note 19, at 210 (asserting that the TRIPs Agreement will cause a further reduction of access to essential drugs constituting a public health concern for developing countries).

31. See generally Weissman, *supra* note 10, at 1085 (examining the concerns of Third World countries in the implementation of pharmaceutical patents); Smith, *supra* note 27, at 211 (commenting on Vietnam's struggles over adopting Western imposed intellectual property laws); Vicente, *supra* note 6 (discussing Argentina's resistance to the imposition of patent protection on pharmaceuticals).

nature of pharmaceutical patents, and the differing viewpoints supporting or contesting enhanced intellectual property rights as it applies to pharmaceutical patents. In addition, an examination of the recent events in Pretoria, South Africa, and their implications, will be undertaken.

The approaching January 1, 2005 deadline for developing countries to comply with the TRIPs agreement,³² will be discussed in Section VI. Additionally, section VI proposes alternative methods of interpreting TRIPs and methods for dealing with the United States' heavy-handed attitude towards developing countries. Section VI also asserts that developing countries, including India, as sovereign nations, should have the right to determine their patent policies in accordance with the health concerns of their people.³³

The imposition of universal standards of patent protection under TRIPs in its current form cannot be justified. Anti-competitive intellectual property rights of industrialized nations, led by United States authorities, provide more benefits to the developed world than to developing countries. Such a high level of protection, particularly as it pertains to medical needs, is neither necessary nor fair.

32. TRIPs Agreement, *supra* note 7, art. 65. Article 65 provides for the transitional arrangements for countries to apply the provisions of the TRIPs. *See id.* All members are given one year, subsequent to the date of entry into force of the WTO Agreement, to implement the TRIPs Agreement. *Id.* art. 65(1). Developing countries are entitled to delay an additional four years before implementing the Agreement. *Id.* art. 65(2). Additionally, a developing country that is required to extend product patent protection to areas of technology that were previously unprotected, is entitled to delay the application in the area of product patents for an additional period of five years. *Id.* art. 65(4). Thus for developing countries which did not previously require product patents for pharmaceuticals, including India, Article 65 provides a ten year transitional period. *See id.* art. 65. Least developed countries were automatically given a ten-year transition period and can request an extension from the Council of TRIPs. *See id.* art. 66. *See also Implications of Uruguay Round, supra* note 7 (explaining that a special transitional arrangement was provided for developing countries that had not previously provided product protection, such as in the pharmaceutical arena); M.A. Kamal, *Role of WTO in Shaping a Balanced Global Economy*, THE INDEPENDENT, Aug. 26, 1999 (distinguishing that while developed countries were required to meet the obligations of TRIPs by 1996, developing countries, which had not previously provided protection to pharmaceuticals, have been given until January 2006 to implement the measurements), available at 1999 WL 21950370.

33. This view is supported by the WHO as noted in a meeting of the World Health Assembly. *See* WHA 52.23, *Strengthening Health*, *supra* note 22. The 52nd World Health Assembly explicitly acknowledges "the sovereign right of each country to adopt national policies appropriate to the specific needs of its people." *Id.*

II. ON INTELLECTUAL PROPERTY LAW

A. *What Is Intellectual Property?*

Intellectual property can be defined as a "property right in an intangible asset—a right in the 'product of the mind.'"³⁴ An example of an intellectual property right, and the focus of this paper, is a patent.³⁵ A patent provides a grant to an inventor of the exclusive use or sale of an invention, thus acting as an incentive for the inventor to work on developing new inventions.³⁶ A patent represents a monetary reward to an inventor by legally excluding those seeking to make, use or sell the inventor's product without permission, thus ensuring maximum profits.³⁷ However, a patent can also be seen as granting a monopoly to the holder,³⁸ and thus the reward presents the danger of legally sanctioned

34. Doris E. Long & Anthony D'Amato, *Introduction*, in *INTERNATIONAL INTELLECTUAL PROPERTY* 12 (Doris Long & Anthony D'Amato eds., 2000) [hereinafter Long & D'Amato, *Introduction*]. See also Smith, *supra* note 27, at 212, 215 (indicating that intellectual property encompasses property status bestowed on expressions, ideas, inventions and creations).

35. Intellectual property has five basic forms: copyright, patent, trademark, trade secrets, and industrial design. See Anthony D'Amato & Doris E. Long, *Introduction*, in *INTERNATIONAL INTELLECTUAL PROPERTY LAW* 1 (Anthony D'Amato & Doris Long eds., 1997) [hereinafter D'Amato & Long, *Introduction*]. For the purpose of this comment I will focus specifically on patents. To be patentable, an invention must be new, useful and non-obvious. *Id.* at 3. A patent is essentially an exclusive monopoly which the government grants to inventors for a limited time period. See *id.* at 4. Patents are obtained by filing an application with the country's patent office and completing various forms as required by the specific Patent Act of the country. See *id.* When an inventor tries to obtain a patent the inventor is trying to gain exclusive rights over the invention, preventing others from imitating the invention and earning profit. See *id.* The purpose behind granting an inventor a limited monopoly, in the form of a patent, is to encourage further innovation thereby promoting the progress of science. See Barrett, *supra* note 9, at 921. By allowing this type of monopoly, the inventors' investment in research and development can be recouped and the inventor is provided with an incentive or a reward to continue with new developments or inventions. See *id.* It is construed as being in the best interest of a government to encourage inventors to file for patents as such actions stimulate and contribute to the country's economic, industrial and technological development. See *id.* Patents are normally limited to a specific term as defined by a country's patent act. See D'Amato & Long, *Introduction*, *supra* at 4. Currently under TRIPs, the patent term has been extended to a period of 20 years. Developed countries viewed this extended term as a substantial accomplishment, while developing countries considered it a loss as they generally prefer short patent terms. See *id.*

36. See Doris E. Long & Anthony D'Amato, *Patents: An Overview*, in *INTERNATIONAL INTELLECTUAL PROPERTY* 45 (Doris Long & Anthony D'Amato eds., 2000) [hereinafter Long & D'Amato, *Patents: An Overview*].

37. See D'Amato & Long, *Introduction*, *supra* note 35, at 1.

38. Donald F. Turner, *The Patent System and Competitive Policy*, 44 N.Y.U. L. REV. 450 (1969), excerpt reprinted in *INTERNATIONAL INTELLECTUAL PROPERTY* 196 (Doris Long & Anthony D'Amato eds., 2000). Cf. John M. Wechkin, Comment, *Drug Price Regu-*

price gouging, allowing for extreme prices, well above the cost of production.³⁹

B. *Diverging Views of Developed and Developing Nations Toward Intellectual Property Rights*

Broad discrepancies exist between developed and developing countries in determining the value that should be given to intellectual property protection.⁴⁰ The main reason for this discrepancy is the perceived bifurcated impact of such protection.⁴¹ Inventors in industrialized nations advocate for strong intellectual property protection. They assert that this protection serves as an incentive for future research and development, allows for recovery of costs, and prevents developing countries from "free riding" on the invention.⁴²

lation and Compulsory Licensing for Pharmaceutical Patents: The New Zealand Connection, 5 PAC. RIM L. & POL'Y J. 237, 237 (1995) (explaining that some claim that patents grant a monopoly power which results in higher prices for patented products and in the area of pharmaceuticals leads to a reduction of availability of essential medicines).

39. See Hurlbutt, *supra* note 16, at 37. Cf. Adelman & Baldia, *supra* note 14, at 510 ("[T]he patent system does not simply generate winners, it also generates losers: those who pay monopoly prices for products that for one reason or another would have been invented in the absence of a patent system.").

40. Long & D'Amato, *Introduction*, *supra* note 34, at 10. See Anthony D'Amato & Doris E. Long, *Common Heritage of Mankind*, in INTERNATIONAL INTELLECTUAL PROPERTY LAW 61 (Anthony D'Amato & Doris Long eds., 1997) [hereinafter D'Amato & Long, *Common Heritage of Mankind*]; Kirsten Peterson, Recent Development, *Recent Intellectual Property Trends in Developing Countries*, 33 HARV. INT'L L.J. 277, 277 (1992). Cf. Sarma, *supra* note 4, at 117 (asserting that "developed countries have a eurocentric, individualistic understanding of property" that fails to appreciate the distinct community understanding of property found in developing countries).

41. Industrialized countries are perceived as possessing the majority of inventors and creators of intellectual property. See Long & D'Amato, *Introduction*, *supra* note 34, at 11. These countries advocate for enhanced protection and assert that the unauthorized use of intellectual property will cause serious financial loss as inventors will be unable to recover their research and development costs. *Id.* However, developing countries, which possess scarce economic resources, argue that intellectual property is merely a means to exploit and dominate poor countries. See *id.* See also Peterson, *supra* note 40 (noting the distinction in views between developing and developed countries).

42. See Long & D'Amato, *Introduction*, *supra* note 34, at 11; Alan S. Gutterman, *The North-South Debate Regarding the Protection of Intellectual Property Rights*, 28 WAKE FOREST L. REV. 89, 92 (1993); McCabe, *supra* note 9, at 56. See generally Adelman & Baldia, *supra* note 14, at 508. Free riding occurs when a country copies patented technology or products from another country. See *id.* at 510. This can occur when a country adopts weak patent protection. *Id.* In the pharmaceutical industry, the wealthy industrialized countries pay for the development of new medicines, while many other countries do not participate in that innovative process. See *id.* India provides an example of a country that has allowed the cost of research and development of pharmaceuticals to fall on the developed world. See *id.* at 511. See also Peterson, *supra* note 40, at 279 (explaining that

Developing countries view the appropriation of knowledge as unfair and detrimental to the development of those nations.⁴³ Many argue that knowledge should be treated as the common heritage of mankind and made available to all.⁴⁴ This is particularly true in regards to patents. The governments of many developing countries have resisted providing full patent protection to inventions or enforcing patent provisions that have previously been enacted.⁴⁵ They assert that they will receive minimal benefits through an extension of protection, and that it is the developed countries that will accrue the maximum benefits.⁴⁶ Additionally, developing countries view the imposition of intellectual property protection as an exercise of foreign control, diminishing their sovereign rights.⁴⁷ In consideration of their limited resources, developing countries feel the imposition of strong intellectual property rights will inhibit their own ability to gain access to new technologies in pursuit of economic growth and competitiveness.⁴⁸ Therefore, these nations resist industrialized countries' demands for implementation and enforcement of such laws.

C. *Intellectual Property Law Favors the Have Nations*

Prior to the Uruguay Round, many developing countries, led by India, argued that GATT was an inappropriate forum to discuss the development of enhanced intellectual property protection.⁴⁹ Developing coun-

for developed nations, who are perceived as possessing the majority of creators and inventors of intellectual property, the unauthorized use of intellectual property represents a financial loss). *But see* Barrett, *supra* note 9, at 913 (remarking that even in the United States free riding is not seen as inherently undesirable; if facilitated under the law it can be beneficial to the public provided it does not seriously interfere with the incentive to invest in research and development).

43. *See* Long & D'Amato, *Introduction*, *supra* note 34, at 11; Sarma, *supra* note 4, at 118.

44. *See* D'Amato & Long, *Common Heritage of Mankind*, *supra* note 40, at 61; Long & D'Amato, *Introduction*, *supra* note 34, at 11.

45. *See* Gutterman, *supra* note 42, at 92; Peterson, *supra* note 40, at 279.

46. *See* Gutterman, *supra* note 42, at 92.

47. *See* Long & D'Amato, *Introduction*, *supra* note 34, at 11; Gutterman, *supra* note 42, at 92; Peterson, *supra* note 40, at 279-80. *See also* Smith, *supra* note 27, at 231 (noting that TRIPs, through the imposition of strong intellectual property rights in developing countries, is potentially problematic as it encourages an economic dependence on industrialized countries).

48. *See* D'Amato & Long, *Common Heritage of Mankind*, *supra* note 40, at 61; Gutterman, *supra* note 42, at 104. *See also* Sarma, *supra* note 4, at 127 (stating that TRIPs detracts from developing countries ability to attain self-sufficiency).

49. *See* Doris E. Long & Anthony D'Amato, *Does Intellectual Property Favor the "Have" Nations?*, in *INTERNATIONAL INTELLECTUAL PROPERTY* 134 (Doris Long & Anthony D'Amato eds., 2000) [hereinafter Long & D'Amato, *Does Intellectual Property Favor the "Have" Nations?*]. *See also* Doris E. Long, *Copyright and the Uruguay Round Agreements: A New Era of Protection or an Illusory Promise?*, 22 *AIPLA Q.J.* 531, 537, 543

tries were reluctant to address intellectual property protection through the GATT, which was viewed as representing the demands of the more powerful "have" nations.⁵⁰ Arguably, ensuring access to international trade is more important to developing countries because of their distinct need for economic growth.⁵¹ Thus, many developing countries were concerned that their needs would not be given sufficient consideration.⁵²

The United States, undoubtedly the biggest proponent of TRIPs, emphasized that the trade concessions, which give developing countries greater access to the markets of industrialized countries, are 'quid pro quo' in exchange for enhanced intellectual property laws.⁵³ For developing countries, this trade-off is potentially dangerous to their well being. At the heart of the debate are the changes to current intellectual property patent law, particularly as it relates to pharmaceutical patents.

Developing countries often make the argument that the sale and manufacture of patented goods does not harm an intellectual property owner.⁵⁴

(1994) (providing that India and Brazil contested the insertion of an intellectual property agreement into GATT); Sarma, *supra* note 4, at 129 (mentioning India's protests against TRIPs).

50. Long & D'Amato, *Does Intellectual Property Favor the "Have" Nations?*, *supra* note 49, at 134. See D'Amato & Long, *Introduction*, *supra* note 35, at 2. The "have" nations, are synonymous with rich, developed, industrialized countries and are perceived as those countries who generated a substantial proportion of the inventions. *Id.* The have-nots are synonymous with countries that do not generate an equivalent amount of intellectual property. *Id.* See also Long, *supra* note 49, at 533, 544 (describing the fundamental conflict between developed and developing countries or the technological haves and technological have-nots in the GATT).

51. See The International Development Research Centre (IDRC) to the House of Commons Standing Committee on Foreign Affairs and International Trade, *Issues of Concern to Canada at Future WTO Negotiations* (April 21, 1999) (prepared by Rohinton Medhora, Senior Specialist), available at <http://www.idrc.ca/tec/wtohoce.html> (on file with author).

52. See *id.*

53. See Mossinghoff, *supra* note 12, at 598 (intimating that the United States engaged in 'linkage-bargain diplomacy' by trading off the GATT multilateral trade negotiations in exchange for increased intellectual property protection); J.H. Reichman, *Compliance with the TRIPS Agreement: Introduction to a Scholarly Debate*, 29 VAND. J. TRANSNAT'L L. 363, 374 (1996) (asserting that even if developing countries relinquished more on intellectual property issues they obtained more in trade provisions). Cf. Sherwood, *supra* note 12, at 493 ("[I]n recent years, the issue of intellectual property protection has been 'married' to international trade").

54. Long & D'Amato, *Does Intellectual Property Favor the "Have" Nations?*, *supra* note 49, at 135-36; Frederick M. Abbott, *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 VAND. J. TRANSNAT'L L. 689 (1989), excerpt reprinted in INTERNATIONAL INTELLECTUAL PROPERTY LAW 11 (Anthony D'Amato & Doris Long eds., 1997). Since intellectual property is intangible, it can be reproduced and used without actually depriving the inventor of the use or possession of the invention. *Id.* The demand for the protection of intellectual property

This is due to the fact that the patent holder is not prevented from making or selling any amount of lawful copies.⁵⁵ No real harm is done when a purchaser buys an unlawful version of a good, which would be priced below the market value, as they would never have been able to afford the legitimate version.⁵⁶ In light of these considerations, the developing countries' dedication to facilitate their economic growth and independence is inhibited by the over-enforcement of intellectual property laws, which favor the "have" nations.⁵⁷

III. THE IMPACT OF MULTILATERAL AGREEMENTS

A. *The Uruguay Round of the General Agreement on Tariffs and Trade and the TRIPs Agreement*

During the period leading up to the Uruguay Round of GATT, many industries dependent on intellectual property protection, including the United States pharmaceutical industry,⁵⁸ began to promote the idea that the GATT negotiations would be an ideal opportunity to gain protection on an international level.⁵⁹ By inserting an intellectual property agreement into the GATT, developing nations dependent on the trade concessions would be forced to change their laws to align with those of the developed countries.⁶⁰

rights is based on the idea that such property naturally belongs to the person who created it. *See id.* The use of intellectual property without compensating the natural owner, is viewed by developed countries as wrong. *Id.*

55. *See Long & D'Amato, Does Intellectual Property Favor the "Have" Nations?*, *supra* note 49, at 135-36.

56. *See id.*

57. *See id.*

58. *See Gutterman, supra* note 42, at 108. The United States pharmaceutical industry has been a large factor in placing intellectual property onto the free trade agenda. *See Weissman, supra* note 10, at 1069. Amongst the world's largest pharmaceutical companies, are Merck, Pfizer, Glaxo Smith Kline, and Eli Lilly. *See Larry Elliott, Putting Profit Before People, THE CANBERRA TIMES*, Feb. 19, 2001, at A11.

59. *See Gutterman, supra* note 42, at 108; Mossinghoff, *supra* note 12, at 598. During the Uruguay round of trade talks the large pharmaceutical companies used their financial muscle and political leverage to lobby for increasing intellectual property patent protection. *See Elliott, supra* note 58, at A11. *Cf. Weissman, supra* note 10, at 1069 (discussing intellectual property in broad terms).

60. *See Mossinghoff, supra* note 12, at 598 (intimating that linkage-bargain diplomacy assured that the intellectual property protection would be incorporated within the GATT multilateral trade negotiations to achieve an agreement that would otherwise be elusive); Weissman, *supra* note 10, at 1084-85 (discussing the need for developing countries to make intellectual property sacrifices in order to attain the benefits of GATT).

B. *The United States as the Primary Supporter of TRIPs*

Developed nations, led by the United States, rallied for the inclusion of TRIPs in the Uruguay Round.⁶¹ By including TRIPs in the Final Agreement, the United States admittedly "created a set of standards enforceable between governments and subject not only to our own trade laws but to multilateral rules."⁶²

The United States points to its own domestic legislation as a basis for demanding strong intellectual property rights, particularly in the area of patent protection.⁶³ The United States' Patent Act provides that for an invention to be patented, it must be novel,⁶⁴ non-obvious⁶⁵ and have utility.⁶⁶ Once these requirements are met, the government grants a patent on behalf of the United States by the Patent and Trademark Office.⁶⁷ Although a patent is intangible, it possesses the attributes of personal property and may be sold or licensed to a prospective user.⁶⁸ The patent is not to be infringed upon during the patent's term. At the end of the patent's term, the exclusive rights are extinguished and the owner of the right, under the patent, can no longer protect the invention.⁶⁹ The

61. See The United States Trade Representative, *The Work of the USTR-Intellectual Property*, at www.ustr.gov/sectors/swtwork.shtml (last visited Feb. 26, 2001) (on file with author). The U.S. House of Representatives approved the GATT legislation on November 29, 1994 and the Senate ratified the accord on December 1, 1994. See *id.* President Clinton signed the bill on December 8, 1994. *Id.* Because of U.S. concerns that some future decisions by the organization may be unacceptable under U.S. laws, a provision in the treaty allows any member to withdraw from the WTO six months after giving notice. See *id.* See Mossinghoff, *supra* note 12, at 598.

62. The United States Trade Representative, *The Work of the USTR-Intellectual Property*, *supra* note 61.

63. U.S. CONST. art. I, § 8, cl. 8. The clause states the Constitution grants Congress the authority to enact legislation: "[t]o promote the progress of [science] by securing for limited [t]imes to . . . inventors the exclusive [right] to their . . . [d]iscoveries." *Id.* This clause is often termed the Patent Clause of the Constitution. See *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 635 (1999). Additionally, the United States Patent Act has been codified in Title 35 of the United States Code. See 35 U.S.C. §1-376 (1994). See also Mossinghoff, *supra* note 12, at 592 (noting that in 1954, Congress codified the U.S. patent statute in Title 35 of the U.S. Code).

64. See 35 U.S.C. §§ 101, 102 (1994).

65. See *id.* § 103.

66. See *id.* § 101.

67. See *id.* § 153.

68. See *id.* § 261. See also Alan M. Fisch, Note, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 J. INT'L TRICS J. 295, 300 (1994). A patent holder is able to sell or license their patent and upon doing so waives any property rights in the patent. See *id.* A compulsory license, allows a person other than the patent holder to manufacture, sell or use the patented invention for a reasonable rate as established by the government. See *id.*

69. See 35 U.S.C. § 271(a) (1994).

United States pharmaceutical industry may hold a patent until it expires, at which time generic producers can sell copies of the drug without the authority of or payment to the patent owner.⁷⁰ Considering the power and magnitude of the United States' pharmaceutical industry, the fact that the government has fought for the inclusion of strong intellectual property protection in its domestic laws is not surprising.⁷¹

1. Special 301

Historically, the United States has unilaterally imposed coercive measures in order to pressure countries to comply with its intellectual property demands. The most utilized measure was implemented in 1988 with the addition of section 182 to the Omnibus Trade Act of 1974,⁷² commonly referred to as "Special 301."⁷³ This initiative of the United States Trade Representative (USTR) provides for an annual Special 301 review mandated by Congress.⁷⁴ The 1988 Trade Act provides that the protection of intellectual property rights is essential for the United States to be internationally competitive.⁷⁵ In light of this consideration, Special 301 permits the United States to intercede directly in countries where piracy is viewed as prevalent or where a government is considered exceptionally tolerant of piracy.⁷⁶ Special 301 provides that the United States, through the USTR may identify and investigate foreign countries that fail to ensure appropriate protection for the intellectual property rights of the United States and to press any country who fails to provide adequate protection through the threat of trade sanctions.⁷⁷ Special 301 gives the

70. See Fisch, *supra* note 68, at 299-300. See also 35 U.S.C. § 154(a)(2) (1994) (establishing a 20 year term for a patent).

71. See Fisch, *supra* note 68, at 299-300.

72. Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, §§ 1301, 1303, 102 Stat. 1107, 1164-76, 1179-81 (1998) (codified as amended in scattered sections of 19 U.S.C. 2411-19) [hereinafter 1988 Omnibus Trade Act] (amending the Trade Act of 1974, Pub. L. No. 93-316, §§ 302(b), 182 (1974)).

73. See *id.*; Judith H. Bello & Alan F. Holmer, "Special 301": Its Requirements, Implementation and Significance, 13 FORDHAM INT'L L.J. 259, 259 (1990); Weissman, *supra* note 10, at 1078.

74. 1988 Omnibus Trade Act, *supra* note 72. See The United States Trade Representative, *The Work of the USTR-Intellectual Property*, *supra* note 61.

75. See 1988 Omnibus Trade Act, *supra* note 72, §1303(a)(1)(A) 102 Stat. at 1179; Bello & Holmer, *supra* note 73, at 260-61.

76. See The United States Trade Representative, *The Work of the USTR-Intellectual Property*, *supra* note 61.

77. Press Release, Office of the United States Trade Representative, USTR Announces Results of Special 301 Out-of-Cycle Reviews (Nov. 8, 2000), available at www.ustr.gov (on file with author); The United States Trade Representative, *The Work of the USTR-Intellectual Property*, *supra* note 61. See 19 U.S.C. §2411 (c) (as amended by Pub. L. No. 103-465, 108 Stat. 4938, Dec. 8, 1994. See also Weissman, *supra* note 10, at 1078

USTR the right to determine if a country through its actions, policies or practice do not measure up to United States standards of intellectual property, which might restrict persons or corporations of the United States from gaining access to their markets.⁷⁸ Countries deemed Priority Foreign Countries (PFCs), are often investigated as the United States feels they create the greatest potential for an adverse impact on United States products because of their practices and policies which prevent intellectual property protection.⁷⁹

Particularly disturbing is the fact that the United States is allowed to make these determinations on its own, without any oversight. The United States, however, views such measures as greatly improving intellectual property standards around the world.⁸⁰

In the Uruguay Round Agreements Act, Special 301 was amended to clarify that even a country in compliance with the obligations of the TRIPs Agreement can be found to deny effective and adequate intellectual property protection.⁸¹ Clearly, this should be viewed as an example of United States unilateralism. Through Special 301, the United States uses the credible threat of unilateral retaliation to ensure that countries comply with its intellectual property regime.⁸² Such unilateral action has no place in the global arena. GATT members, particularly the developing countries, have complained that the United States' use of Special 301, "violates the spirit, if not the letter, of GATT."⁸³ The United States has

(pointing out that some speculate that the USTR has focused its attention on countries such as India and Brazil because of their role in advancing the developing countries' demands in the Uruguay round of negotiations).

78. See Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment, 66 Fed. Reg. 10,3640 (Jan. 16, 2001); Press Release, Office of the United States Trade Representative, USTR Announces Results of Special 301 Out-of-Cycle Reviews, *supra* note 77. See also Bello & Holmer, *supra* note 73, at 261.

79. See Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment, 66 Fed. Reg. 10,3640 (Jan. 16, 2001) (noting that it is the responsibility of the USTR to determine PFC's who will be subject to investigation).

80. See The United States Trade Representative, *The Work of the USTR-Intellectual Property*, *supra* note 61.

81. See Press Release, Office of the United States Trade Representative, USTR Announces Results of Special 301 Out-of-Cycle Reviews, *supra* note 77.

82. See Bello & Holmer, *supra* note 73, at 259. See also Weissman, *supra* note 10, at 1079 (recognizing that the main target of USTR sanctions have been third world countries with developing pharmaceutical industries such as India, Argentina, Brazil, Taiwan and Thailand).

83. Robert J. Pechman, Note, *Seeking Multilateral Protection for Intellectual Property: The United States "TRIPS" Over Special 301*, 7 MINN. J. GLOBAL TRADE 179, 199 (1998). See also Jack Egan, *Eaton Vance Greater India*, U.S. NEWS (Jan. 24, 2000), available at [wysiwyg://149/http://www.usnews.com/usnews/issue/000124/nycu/fund5.htm](http://www.usnews.com/usnews/issue/000124/nycu/fund5.htm) (last visited Sept. 30, 2000) (on file with author). Developing Nations have expressed concerns that the WTO may be becoming an agent of the U.S. and developed countries. See *id.* India's

no right to act as enforcement police to developing countries; despite its continuing policies to the contrary. This is particularly true as the USTR focus encompasses whether countries are in compliance with their WTO TRIPs obligations.⁸⁴

While developed countries argue that a strong intellectual property system acts to the advantage of a country, such an argument fails to take into account the different needs of poorer, developing nations.⁸⁵ Although the United States sought and achieved a dispute settlement mechanism to secure compliance,⁸⁶ it has continued to use Special 301 to impose unilateral sanctions against countries.

In late April of 2000, the USTR released its annual report identifying foreign countries, which deny adequate and effective intellectual property rights.⁸⁷ Fifty-nine countries were identified as intellectual property evaders.⁸⁸ Sixteen of those countries, including India, were placed on the Priority Watch List.⁸⁹ Due to complaints against such unilateral action, extreme pressure has been placed on the United States, which has taken small measures to appear to respond to developing countries' concerns.⁹⁰ In the face of current AIDS controversy in South Africa, the large pharmaceutical companies and the United States government found it necessary to do some image control.⁹¹ In May 2000, President Clinton signed

Commerce and Industry Minister has warned developing nations to resist moves by developed nations that threaten sanctions to reduce the competitiveness of the developing nations. *See id.*

84. Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment, 66 Fed. Reg. 10,3640 (Jan. 16, 2001).

85. *See Fidler, supra* note 19.

86. *See* America and the World Trade Organization, United States Trade Representative, 6 (1998), available at www.ustr.gov. (on file with author).

87. *See* Identification of Countries that Deny Adequate Protection, or Market Access for Intellectual Property Rights Under Section 182 of the Trade Act of 1974, 65 Fed. Reg. 89,26652 (May 8, 2000).

88. *Id.*

89. The countries placed on the watch list were Argentina, the Dominican Republic, Egypt, the European Union, Greece, Guatemala, India, Israel, Italy, Korea, Malaysia, Peru, Poland, Russia, Turkey, and Ukraine. *See id.* Other countries were placed on the Watch List, or the Potential Priority Foreign Country list. *See id.* In this report the USTR announced that it would also initiate WTO dispute settlement cases against Argentina and Brazil. *Id.*

90. Press Release, Office of the United States Trade Representative, The Protection of Intellectual Property and Health Policy, (Dec. 1, 1999), available at www.ustr.gov (on file with the author).

91. Five major pharmaceutical companies, Bristol-Myers Squibb, Merck, Boehringer-Ingelheim, GlaxoWellcome and F. Hoffman, entered a cooperative effort to accelerate access to HIV/AIDS care and treatment in developing countries. *See* Press Release, Office of the United States Trade Representative, USTR Barshefsky Welcomes Drug Company-United Nation Announcement to Improve Access to HIV/AIDS Drugs (May 11, 2000),

an executive order giving the USTR flexibility to provide life-saving drugs to afflicted populations in South Africa.⁹² While South Africa has now been removed from the Special 301 watch list,⁹³ the United States has not applied this action uniformly to all developing countries. Although the President's recent actions seem to indicate that the United States is easing the burden on developing countries, in early January 2001, the office of the USTR provided notice that India was in danger of having its duty-free access for imports from India withdrawn.⁹⁴

C. *India as the Leader of the Developing Nations' Opposition to TRIPs*

India led the unsuccessful fight against the establishment of a world intellectual property regime, under the GATT.⁹⁵ In particular, India opposed the intellectual property protection of pharmaceuticals.⁹⁶ India argued that patenting much-needed medical products would make them unattainable to consumers in developing countries.⁹⁷ Despite the con-

available at www.ustr.gov (on file with author). Realistically, this is just a token gesture made in the face of increasing pressure from developing countries, and activists groups. While the drug companies previously had the full support of the U.S. government, recently the Clinton administration took steps to stop pressing South Africa to change its patent policy regarding pharmaceuticals. *Id.* See also Helene Cooper, Rachel Zimmerman & Laurie McGinley, *Patents Pending: Aids Epidemic Traps Drug Firms in a Vice: Treatment vs. Profits*, WALL ST. J., Mar. 2, 2001, A1, A6.

92. See Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6 (noting that, in order to qualify, the actions had to be consistent with the WTO TRIPs Agreement).

93. This was done as part of a joint initiative between the USTR and Health and Human Services. See Press Release, Office of the United States Trade Representative, The Protection of Intellectual Property and Health Policy, *supra* note 90. The cooperative approach on health-related intellectual property issues is meant to ensure that trade law related to intellectual property remains flexible in response to the public health crisis. *Id.* The USTR, Barshefsky, stated the belief that "sound public health policy and intellectual property are, and must continue to be, mutually supportive." *Id.* While the statement seemed to recognize that health emergencies might require special measures, no firm commitment, other than to protect U.S. trade law relating to intellectual property in accordance with TRIPs, was provided. See *id.* The only commitment the USTR gives to addressing a health crisis in a country, is to "seek and give full weight to the advice of [Health and Human Services] regarding the health considerations involved." *Id.*

94. See Generalized System of Preferences (GSP): Deadline for Submitting Public Comments on Modification of Duty-Free Treatment for Certain Products Imported from India, 66 Fed. Reg. 13,5521 (Jan. 19, 2001) (announcing that India may have its duty-free benefits on some products removed).

95. See Long & D'Amato, *Introduction: A Trip Begins*, *supra* note 14, at 7

96. See *id.*

97. See *id.* See also Sebastian Dominic, *Patents and Indian Pharmaceuticals Industry*, (Jan. 21, 1999) (stating that prices of drugs will go up by three to five times, and only ten percent of the population will be able to afford them), at http://www.suite101.com/article.cfm/business_in_india/14753 (last visited Sept. 30, 2000).

cerns of India and many other developing countries, the TRIPs Agreement was placed on the table, giving developing countries little choice. Essentially, these countries were forced to either agree to the version of GATT including TRIPs, or be excluded from the benefit of GATT entirely.⁹⁸ Unfortunately, the trade-off placed developing countries and public health policy at the whim of the developed countries once again. Despite its opposition to TRIPs, India signed on.⁹⁹

1. The WTO Provides Developed Nations with an Unfair Advantage

Since the creation of the WTO, United States exports of goods and service have risen by \$170 billion and by \$65 billion, respectively.¹⁰⁰ Developing countries have become increasingly concerned about the WTO's ability to act for all of its members.¹⁰¹ One commentator wrote:

Even though the majority of the 135 members of the WTO are poor countries, they are being virtually held hostage. Third World countries . . . [are] compelled to go along with the developed countries because most of these poor countries are dependent on bilateral trade relations with one or more developed countries.¹⁰²

Increasingly, the WTO appears to be becoming a tool for the developed nations. In early January 2000, Murasoli Maran, the Indian Commerce and Industry Minister, stressed that developing countries must form a unified front against the WTO.¹⁰³ Maran encouraged developing nations to press the WTO to address their fears, anxieties and insecurities by reforming the organization.¹⁰⁴ The WTO has been labeled the

98. See TRIPs Agreement, *supra* note 7, art. 70.8, 70.9.

99. India, along with 110 other countries, authenticated the results of the Uruguay Round by signing the Final Act at Marrakesh on April 15, 1994. See Final Act, *supra* note 8. See also Tomar, *supra* note 14, at 591.

100. See America and the World Trade Organization, United States Trade Representative, *supra* note 86, at 9 (illustrating that Americans are extremely competitive in export fields including medicines).

101. See New Economy Information Service, *Is this Just a North/South Debate?* (Dec. 8, 1999) [hereinafter *Is this Just a North/South Debate?*], at http://www.wtowatch.org/library/ad..._This_Just_a_NorthSouth_Debate.htm (last visited Sept. 30, 2000) (on file with author).

102. *Id.* (commenting on the Seattle WTO round).

103. Agence France Presse, *India Urges Developing Countries to Close Ranks Against WTO* (Jan. 10, 2000), at <http://www.wtowatch.org/news/index.cfm?ID=1378> (last visited Sept. 30, 2000) (on file with author).

104. See *id.*

"Wicked Trade Organization," and has been accused of attempting to police the world economy to the benefit of industrialists.¹⁰⁵

2. The WTO Dispute Resolution Mechanism

The WTO is meant to be a partnership of equals; however, it has been noted that "some members are more equal than others."¹⁰⁶ Ideally, any member of the WTO may seek redress against another member through the use of its dispute resolution panel.¹⁰⁷ Realistically, this remedy is only available to those members who can afford this lengthy and expensive process.¹⁰⁸ Clearly, this process favors industrialized countries. Another impediment to the use of the dispute resolution process is the fact that many developing countries are unwilling to file a complaint against a country that they may be dependent upon for aid.¹⁰⁹ The difficulties that developing countries face in bringing cases to the WTO generally leave them defenseless to developed countries' abuses, while any minor transgression by a developing country is brought to the Dispute Settlement Body (DSB).¹¹⁰ Developing countries must choose their battles carefully.

a. The United States v. India at the WTO

Beginning in 1996, the United States began utilizing the WTO's DSB to file proceedings against India for alleged violations of the TRIPs Agreement.¹¹¹ Despite the transition period provided for developing countries,

105. WTOWATCH.org, *WTO Director General Faces Protestors in India* (Jan. 11, 2000), available at <http://www.wtowatch.org/news/index.cfm?ID=1396> (on file with author).

106. International Development Research Centre, *Issues of Concern to Canada at Future WTO Negotiations*, *supra* note 51.

107. *See id.* *See also* The United States Trade Representative, *The Work of the USTR-Intellectual Property*, *supra* note 61 (noting that the United States has been aggressively and successfully using the dispute settlement process of the WTO to assert its rights).

108. International Development Research Centre, *Issues of Concern to Canada at Future WTO Negotiations*, *supra* note 51. *Cf.* Weissman, *supra* note 10, at 1095. The dispute settlement mechanism will likely impose severe pressure on countries to alter their patent systems. *See id.* Any sanctions will likely be detrimental to poor developing countries. *See id.*

109. International Development Research Centre, *Issues of Concern to Canada at Future WTO Negotiations*, *supra* note 51.

110. *See id.*

111. Request for the Establishment of a Panel, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Nov. 8, 1996, WT/DS50/4 (1996), available at 1996 WL 908592; Chitra Subramaniam, *WTO Panel Charges India with Non-Compliance with TRIPs Commitment*, Financial Express: Indian Express Newspapers (Bombay) Ltd. (Aug. 13, 1997), available at <http://www.expressindia.com/fe/daily/19970813/22555213.html> (on file with author). *Cf.* TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 32, art. 65, 66 (providing all developing countries, including India, are entitled to a 10

the United States asserted that certain provisions of TRIPs should be immediately implemented.¹¹² The United States' submission contended that India's failure to comply would substantially damage the United States pharmaceutical industry.¹¹³ In September, 1997, the Dispute Settlement Panel determined that India had failed to comply with its TRIPs obligations.¹¹⁴ India subsequently filed an appeal to the DSB, arguing that the requirements of TRIPs could not be applied to developing countries until the January 1, 2005 transition date, and that the panel was interpreting the provisions in TRIPs incorrectly as applied to developing countries.¹¹⁵ The appellate body declined to find in India's favor and determined that the measures India had taken were inadequate to meet its

year transition period to enact the intellectual property provisions of TRIPs, ending January 1, 2005).

112. In the action brought to the DSB, the United States stated that India's laws were inconsistent with the requirements of TRIPs, including Articles 27, 65, and 70. *See* Request for the Establishment of a Panel, *supra* note 111. The request was specifically relating to provisions on Exclusive Marketing Rights (EMRs) and mailbox system. *See id.* *See* Subramaniam, *supra* note 111.

113. First Submission of the United States of America, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Mar. 6, 1997, available at 1997 WL 113721. The United States asserted that India failed in its attempt to implement an EMR system and to establish a mailbox, wherein U.S. patent holders could apply for patents. *See id.* at *1. Specifically the U.S. cited India for its failure to conform with Article 70.8 and Article 70.9. *Id.* The United States argued that even though developing countries are entitled to a ten year transition period, they must establish a system allowing applications for product patent protection to be filed during the transition period, to be examined at a later date, but based upon the date of application (the mailbox). *See id.* The U.S. also asserted that developing countries were required to grant qualifying applicants exclusive marketing rights for pharmaceutical products, for a period of up to five years. *See id.* Although the U.S. submission discusses that the Indian President had promulgated a Patents Ordinance in 1994, and that the government had introduced a Patents Bill in 1995, to amend the laws, the U.S. was dissatisfied with the lack of supplemental legislative action to ensure implementation of the changes. *See id.* at *1-2. In light of India's "failure" to effect changes in their laws the U.S. claims that India is inflicting damage on U.S. industries. *Id.* Specifically, the U.S. submission claimed that their research based pharmaceutical companies lose approximately \$500 million a year because of India's failure to provide pharmaceutical product patent protection. *Id.* at *2. This figure has not been corroborated by the government. *Id.*

114. *See* Report of the Panel, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Sept. 5, 1997, WT/DS50/R (1997), available at 1997 WL 556224, for a detailed report of the panel's finding.

115. *See* Notification of an Appeal, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Oct. 16, 1997, WT/DS50/6 (1997), available at 1997 WL 644454. In its appeal, India argued that the Panel erred in requiring the examination of foreign patent applications, under the mailbox provisions of Article 70.8, prior to the end of the ten-year transitional period. *Id.* at *1. India asserted that "a proper interpretation of the ordinary meaning, context and object and purpose of Article 70.8 and on the basis of the negotiating history" India had not violated its TRIPs obligations. *Id.* at *2.

TRIPs requirement as of January 1, 1995.¹¹⁶ Although the panel had room to interpret the effective dates positively for India and all developing nations, it chose to support the desire of the United States.

India is faced with little choice but to comply with the WTO panel's instructions to pass legislation consistent with the TRIPs, in order to maintain its GATT trade benefits.¹¹⁷ India subsequently made reasonable efforts to conform to the requirements of the panel as provided for in status reports by India to the panel.¹¹⁸ In April 1999, amendments to the

116. See Report of the Appellate Body, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Dec. 19, 1997, WT/DS50/AB/R (1997), available at 1997 WL 781259. Under Indian law, international treaty obligations are not binding by their own force, until appropriate legislative or executive action has brought them into force. See Report of the Panel, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Aug. 24, 1998, WT/DS79/R (1998), available at 1998 WL 527064, at *3.

117. See Foster, *supra* note 26, at 313 (noting that the reason India signed onto TRIPs was to acquire the GATT benefits of reduced textile tariffs). See also Anju Ghangurde, *Patent Experts Sound Caution on EMR Issue*, Financial Express: Indian Express Newspapers (Bombay) Ltd. (Nov. 25, 1998) (commenting on patent experts cautions to legislators in India about the nature of the requirements being implemented), available at <http://www.indian-express.com/fe/daily/19981126/33055464p.html> (last visited Sept. 30, 2000).

118. India and the United States, through bilateral negotiations on April 21, 1998, agreed that fifteen months constituted a reasonable period for implementing the recommendations of the DSB. See Communication from India, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Nov. 12, 1998, WT/DS50/10 (1998), available at 1998 WL 791621. In January, 1999, the Patents Amendment Ordinance was promulgated by India to amend its Patents Act to comply with the obligations contained in the TRIPs Agreement. See Communication by India, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Jan. 14, 1999, WT/DS50/10/Add.1 (1999), available at 1999 WL 14039. In this communication, India updated the panel about the Patents (Amendment) Ordinance as promulgated on January 8, 1999. *Id.* Additionally India explained that a Bill to replace the ordinance would be introduced in the Budget Session of Parliament commencing in late February, 1999. *Id.* As per the Indian Constitution, an ordinance is effective only for a period of six weeks from the re-assembly of Parliament. *Id.* However, an ordinance can expire before the six week period if both houses of parliament, the Lok Sabha and the Rajya Sabha, pass resolutions of disapproval. See *id.* Most importantly, India assured the panel, that the matter would remain in the legislature until the legislation received Parliament's approval. *Id.* Despite India's status report the United States, joined by the European Community, filed another complaint against India with the DSB regarding concerns about the ordinance. See Communication from the Permanent Mission of the United States, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Jan. 20, 1999, WT/DS50/11 (1999), available at 1999 WL 20262; Request by the European Communities and its Member States Regarding Consultations by the United States, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Feb. 4, 1999, WT/DS50/12 (1999), available at 1999 WL 48737. India responded by restating that the ordinance was promulgated, and that a bill would replace it when the Indian Parliament returned to session in the fourth week of February. See Communication from the Permanent Mission of India, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Feb. 5, 1999, WT/DS50/10/Add.2 (1999), available at 1999 WL

Patents Act were passed by both houses of the Indian Parliament and were approved by the President, placing India in full compliance with the recommendations of the panel.¹¹⁹

b. The WTO Upholds United States Unilateralism

In a separate dispute, the WTO upheld the right of the United States to use unilateral trade sanctions through its 301 laws.¹²⁰ The latest ruling on 301 laws makes it clear that the WTO is not attempting to prevent unilateral trade sanctions, but uphold them. When India signed on to the WTO in Marrakesh, one of the main justifications was that the WTO, as a multilateral rule-based system, would render illegal the use of unilateral trade sanctions through instruments like the 301 clauses.¹²¹

With rulings such as these it becomes increasingly apparent that the WTO is a body dominated by the United States, while its trade rules uphold a system of economic dictatorship.¹²² This relationship is visibly ap-

58731. The Indian Parliament returned to session on February 22, 1999. See Communication from the Permanent Mission of India, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Mar. 9, 1999, WT/DS50/10/Add.3 (1999), available at 1999 WL 125361. In April, 1999, India further reported that the government had introduced a Bill in the Indian Parliament to amend the Patents Act, 1970. See Communication from the Permanent Mission of India, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Apr. 16, 1999, WT/DS50/10/Add.4 (1999), available at 1999 WL 231665.

119. Communication from the Permanent Mission of India, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Apr. 16, 1999, WT/DS50/10/Add.4 (1999).

120. See Report of the Panel, *United States-Sections 301-310 of the Trade Act of 1974*, Dec. 22, 1999, WT/DS152/R (1999) (allowing the United States to institutionalize unilateral trade sanctions). See also WTO Dispute Settlement Proceeding Regarding Sections 301-310 of the Trade Act of 1974, as Amended, 64 Fed. Reg. 55,14037-38 (Mar. 23, 1999). The EC contends that sections 301-310 are inconsistent with obligations of the U.S. under the Dispute Settlement Understanding mechanism (DSU), the Marrakesh Agreement and the GATT 1994. *Id.* The EC made a claim that the Trade Act sections 301-310 impose: "specific, strict time limits" that allow the United States to make unilateral determinations and impose trade sanctions against WTO members. *Id.* "Specifically the EC alleges the United States legislation is inconsistent with the obligations of the U.S. under Articles 3, 21, 22, and 23 of the DSU; Article EVI: 4 of the Marrakesh Agreement establishing the WTO; and Articles I, II, III, VIII, and XI of the GATT 1994." *Id.*

121. See Dr. Vandana Shiva, *WTO Defends Economic Dictatorship by Upholding Unilateral Trade Sanctions and U.S. 301 Laws* (Dec. 24, 1999), available at <http://www.wtowatch.org/news/index.dfm?ID=1347> (last visited Sept. 30, 2000) (on file with author).

122. See *id.* This view is also held by some political leaders in the United States. See Ralph Nader, *Fair Trade*, at <http://www.votenader.com/issues/fairtrade.html> (last visited Apr. 7, 2001). Ralph Nader, leader of the Green Party and presidential candidate in the 2000 United States Presidential election stated "'Free trade' is a misnomer. Monopoly patents are not free trade; they're trying to convert all sorts of natural knowledge into

parent when referencing the USTR *Report on America and the WTO*, which states that the United States benefits from the dispute settlement process "by having a set of rules to hold other countries accountable for their trade actions."¹²³

It is time to stop describing WTO rules as offering multilateral protection against United States unilateralism, and see them for what they are—the globalization of 301 laws, and instruments for forcing open markets to United States corporations at any cost, including the destruction of livelihoods, the environment, and human health. Many developing nations are justifiably suspicious of the WTO.¹²⁴ The common feeling is that the WTO is a tool the world powers can use to control the progress of developing countries by dominating their trade markets and exports through the use of monopoly patents.¹²⁵ Arguably, the WTO is merely a prelude to the imposition of the United States' governed New Economic Order in the World.¹²⁶

This belief that intellectual property protection, through the TRIPs as administered by the WTO, favors the "have" nations has become particularly controversial as it relates to patent protection of pharmaceuticals. Patent owners contend that a lack of patent protection will result in lost revenue leading to a lack of desire to fund new drug research.¹²⁷ Furthermore, they argue that in the absence of patent protection many low-quality

intellectual property, 20-year patents. That's not free trade and the rest of it is corporate managed trade." *Id.*

123. America and the World Trade Organization, United States Trade Representative, *supra* note 86, at 13 (emphasis added). In answer to a question on whether U.S. sovereignty would be affected by the WTO rules or dispute settlement process the USTR responded that:

The findings of a WTO dispute settlement panel *cannot* force us to change our laws. Only the United States determines exactly how it will respond to the recommendations of a WTO panel, if at all. If a U.S. measure is ever found to be in violation of a WTO provision, the United States may on its own decide to change the law; compensate a foreign country . . . or do nothing (emphasis added) . . . But America retains full sovereignty in its decision of whether or not to implement a panel recommendation.

Id.

124. *Patents: Private Rights and Public Interests*, MARKET LETTER, Nov. 2, 1992, [hereinafter *Patents: Private Rights and Public Interests*], available at 1992 WL 2794546.

125. *See id.* For poor developing countries, whose health care systems must attempt to provide pharmaceuticals for those who cannot afford them, a patent is viewed as conferring a monopoly, which leads to high prices and places drugs further out of the reach of the poor. *See id.*

126. *Is this Just a North/South Debate?*, *supra* note 101 (listing the concerns of China, Malaysia, Pakistan, Romania, South Korea, India, Sri Lanka, Syria, and Brazil).

127. *See* Doris E. Long & Anthony D'Amato, *The AIDS Drugs Controversy*, in INTERNATIONAL INTELLECTUAL PROPERTY 126 (Doris Long & Anthony D'Amato eds., 2000) [hereinafter Long & D'Amato, *The AIDS Drugs Controversy*]; Mossinghoff, *supra* note 12, at 599.

ity inefficacious or harmful drugs will enter the market due to a lack of quality control.¹²⁸ On the other side of the spectrum, many developing countries assert that increased competition, created by a non-existent or ineffective patent regime, will produce lower prices on medicines, a priority for their people.¹²⁹ Currently, the patenting of essential medicines places them outside the reach of poor countries and only enriches the coffers of the developed world. India's patent policy is one system that has attempted to keep pharmaceuticals out of the hands of intellectual property protectionists.

IV. THE HISTORY AND CURRENT STATUS OF INDIA'S PATENT POLICIES RELATING TO PHARMACEUTICALS

A. *The Road to the Indian Patent Act of 1970*

India gained independence in 1947, after over one-hundred years of imperialism as a colony under the British Empire.¹³⁰ At the time of independence, India only controlled ten percent of its pharmaceutical market.¹³¹ Its drug prices were among the most expensive in the world due to foreign corporations controlling the remaining ninety percent of the market.¹³² Between 1967 and 1970 applications for patents by foreign nationals exceeded applications of Indians by over 340%.¹³³ Independent India acted to reverse this situation by implementing protectionist measures on pharmaceutical patents.¹³⁴

India developed the Indian Patents Act of 1970¹³⁵ to increase the indigent population's access to pharmaceuticals, while simultaneously devel-

128. See Long & D'Amato, *The AIDS Drugs Controversy*, *supra* note 127, at 126.

129. See *id.*

130. See Tomar, *supra* note 14, at 580.

131. See *id.* at 582.

132. See *id.* See also Adelman & Baldia, *supra* note 14, at 526 (providing that during that time the cost of medicines in India were among the highest in the world).

133. Koshy, *supra* note 25, at para. 12.

134. See Adelman & Baldia, *supra* note 14, at 519, 526-27 (explaining that India justified these protectionist measures as necessary to combat foreign monopolistic prices, to ensure that inventions were worked in India and to establish a local industry in India).

135. Patents Act, 1970, 27 INDIA A.I.R. MANUAL 450 (1979) [hereinafter Patents Act]. Under the Patents Act, India recognizes patents under a fourteen-year period of protection. See *id.* at § 53 (1)(b). However, it provides an exception in three areas: food, chemicals and pharmaceuticals, where it recognizes only a process patent for a period of seven years. See *id.* at § 5(a)-(b), 53 (1)(a). See also Adelman & Baldia, *supra* note 14, at 519, 526-27 (noting that the fourteen year patent life was six years shorter than the *international* standard (emphasis added)); Koshy, *supra* note 25, at para. 3-11 (outlining the Patents Act of 1970 as it applies to pharmaceuticals).

oping a research and development initiative among Indian nationals.¹³⁶ India used protectionist provisions in the Patent Act to assist in the development of the pharmaceutical industry by making new medicines at affordable prices and by making those medicines readily available to the public ensuring its national development at the expense of foreign corporations.¹³⁷ The 1970 Act only provided pharmaceutical patents for the process by which a product was made and not the end product itself.¹³⁸ Thus, if an Indian pharmaceutical company could find an innovative or new way to make the exact same product as offered by a brand name company, that product was deemed to be acceptable and in accordance with the Act.¹³⁹

Due to weak patent laws, Indian pharmaceutical companies have been able to reproduce existing drugs at a rapid pace and low cost, which enables them to compete in both foreign and domestic markets.¹⁴⁰ Additionally, due to weak enforcement policies, Indian owned pharmaceutical companies were generally not concerned about issues of legal infringement or potential litigation expenses.¹⁴¹ Indian pharmaceutical companies have been able to curb the domination of foreign corporations in the domestic market, providing India with more independence in its economic and political sectors.¹⁴²

In the last fifty years, India has lowered pharmaceutical prices and since 1996, Indian-owned pharmaceutical companies comprise 85% of the domestic market while the remaining 15% is controlled by pharmaceutical companies from the United States and Europe.¹⁴³ India has resisted implementation of the TRIPs Agreement for fear that the Agreement would reverse the course of history and cause it to revert to being a dependent nation.¹⁴⁴

136. See Tomar, *supra* note 14, at 582 (commenting on the increased independence the Indian pharmaceutical market felt after India won its independence).

137. See Adelman & Baldia, *supra* note 14, at 526; Koshy, *supra* note 25, at para. 12.

138. Patents Act, *supra* note 135, § 5(a)-(b), 53(1)(a). See Koshy, *supra* note 25, at para. 8; *Indian Company Advances Globally With Copy Drugs*, ASIAN WALL STREET JOURNAL, Sept. 23, 1993, available at 1993 WL-WSJA 2008768. See also Weissman, *supra* note 10, at 1073 (remarking that until recently, India only provide process patents for pharmaceuticals).

139. Cf. Koshy, *supra* note 25, at para. 15 (noting that the Indian Patent Act of 1970 did not provide product patents for pharmaceuticals).

140. See Tomar, *supra* note 14, at 582.

141. See *id.*

142. See *id.*

143. See *id.* at 582-83.

144. See *id.* at 583. See also Koshy, *supra* note 25, at para. 36, 37. The Indian government provides free pharmaceuticals at public sector hospitals to the poor who are defined as one-fifth of the urban and one-third of the rural population. See *id.* at para. 36 n.121 (citing HEINZ REDWOOD, NEW HORIZONS IN INDIA: THE CONSEQUENCES OF PHARMACEU

B. *India and Its Current Patent Regime*

Currently, the population in India surpasses one billion people.¹⁴⁵ This population is packed into a small area of only 1,269,338 square miles.¹⁴⁶ India's incredible population density contributes to its high poverty level therefore increasing the need for low-priced necessities, such as pharmaceuticals.¹⁴⁷ Thus, there is a high demand on the pharmaceutical industry and the Indian government to provide medical supplies to the population at affordable prices.¹⁴⁸

The United States, along with its pharmaceutical corporations, has sought to have this changed by requiring product patents in addition to process patents through the TRIPs agreement.¹⁴⁹ Therefore, if the end-product of the Indian company is the same as the end-product of a brand name company, it should be a violation of patent law because it is the same product.¹⁵⁰ India, like most developing countries, has fought against the imposition of product patents.¹⁵¹

For India, the establishment of a strict patent system is unlikely to stimulate growth or encourage research and development as industrialized countries assert. Rather, India is concerned that increased protection will have the opposite effect and actually diminish the promotion of domestic technology, research and development.¹⁵² India asserts that all GATT/WTO countries should be allowed to focus on their individual develop-

TICAL PATENT PROTECTION 24 (1994)). Requiring TRIPs style patents on essential medicines will lead to price increases that could bankrupt the health care system. *See id.*

145. *See* Office of the Registrar General of India, *supra* note 23 (stating that the population of India on March 1, 2001 was 1,012,395,934).

146. *See* Tomar, *supra* note 14, at 580-81. Approximately 320 million Indians lived below the poverty line in 1993. *Id.* In comparison, the United States is three times larger, in size, with a population of only two-hundred and fifty million dispersed across the country. *Id.* at 581.

147. *See id.* at 581. Illness and early death go hand in hand with poverty. *See* Sarah Boseley, *Trade Terrorism- U.S. Attempts to Stop Developing Countries Producing Cheap AIDS Drugs Have Become a Political Time Bomb*, THE GUARDIAN, Aug. 11, 1999, at <http://www.accessmed-msf.org> (last visited Feb. 26, 2001) (on file with author).

148. Tomar, *supra* note 14, at 581.

149. Elliott, *supra* note 58, at A11.

150. *See id.*

151. *See generally*, Koshy, *supra* note 25. Notably, developing countries such as India are not the only protectionist nations as to pharmaceuticals. *See id.* at para. 14. Until recently, many developed countries also employed restrictive intellectual property laws. *See id.* Canada did not provide product patents on pharmaceuticals until 1987 and allowed compulsory licenses for pharmaceuticals until 1991. *See id.* *See also* Adelman & Baldia, *supra* note 14, at 511 (stating that Canada formerly sustained weak pharmaceutical patent laws); Wechkin, *supra* note 38, at 243 (commenting on the protectionist stance of New Zealand and Canada).

152. *See* Gutterman, *supra* note 42, at 132.

mental needs instead of pursuing an intellectual property system that favors developed countries.¹⁵³

V. THE CASE FOR AND AGAINST PHARMACEUTICAL PATENTS IN DEVELOPING COUNTRIES

TRIPs, administered by the World Trade Organization (WTO),¹⁵⁴ requires that all signatory countries grant patent protection to pharmaceutical products.¹⁵⁵ Previously, several developing and developed countries

153. *See id.*

154. TRIPs Agreement, *supra* note 7. *See* Weissman, *supra* note 10, at 1094. The World Trade Organization (WTO), was established as a result of the final round of the General Agreement on Tariffs and Trade negotiations, also known as the Uruguay Round. *Id.* The WTO is responsible for monitoring national trading policies, handling trade disputes, and enforcing the GATT agreements, which are designed to reduce tariffs and other barriers to international trade. *Id.* It has far greater power to mediate trade disputes between member countries, through the inclusion of a dispute resolution mechanism to review and resolves disputes. *Id.*

155. *See* TRIPs Agreement, *supra* note 7, art. 27. TRIPs mandates broad subject matter protection, bringing classes of inventions that had been excluded from patent protection in a number of developing countries, such as agricultural chemicals and pharmaceuticals, within world wide patent protection. *See id.* Article 27 details what is patentable subject matter and in pertinent part provides:

(1) Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or process, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this article, patents shall be available and patent rights enjoyable without discrimination . . .

(2) Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

(3) Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological process. . .

Id. (footnote omitted). TRIPs also mandates the provision of a broad, uniform range of rights. *See id.* art. 28. Article 28 provides:

(1) A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling or importing for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling or importing for these purposes at least the product obtained directly by that process.

had excluded medicines from being patented.¹⁵⁶ The TRIPs Agreement however, made pharmaceutical patents a requirement for all members of the WTO.¹⁵⁷ TRIPs established a number of minimum standards, including granting twenty-year patent protection to pharmaceuticals.¹⁵⁸ As a result, pharmaceutical companies are not only able to control access to patented drugs, but are allowed the freedom to set prices for those products.¹⁵⁹ Developing countries assert that the required protections give those companies free reign over profits to the detriment of the poverty-stricken populations of the developing world.¹⁶⁰ However, drug companies claim that such prices are necessary in order to recoup research and development costs, as well as future research costs.¹⁶¹

Despite these provisions, some developing countries, including India, have refused to extend patent protection to pharmaceuticals.¹⁶² Many developing countries have also attempted to utilize loopholes, such as compulsory licenses and parallel imports provided for in TRIPs, to avoid the patent provisions.¹⁶³ TRIPs Article 31, meant to be one such loop-

(2) Patent owners all also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Id. (footnote omitted). But see TRIPs Agreement, *supra* note 7, art. 28 n.6. Although Article 28(1)(a) of TRIPs confers an exclusive right of importation, this right "in respect of the use, sale, importation or other distribution of goods is subject to the provisions of Article 6." *Id.* For a detailed discussion on parallel imports and the implications of Article 6, see *infra* note 166.

156. See Elliott, *supra* note 58, at A11.

157. TRIPs Agreement, *supra* note 7, and text accompanying *supra* note 155, art 27, 28. See Elliott, *supra* note 58, at A11; Médecins Sans Frontières, *Report to Thailand*, *supra* note 22.

158. See TRIPs Agreement, *supra* note 7, art. 33. Article 33 provides:

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.

Id. (footnote omitted). See also Médecins Sans Frontières, *Report to Thailand*, *supra* note 22.

159. See Elliott, *supra* note 58, at A11 (asserting that the four large pharmaceutical firms act as a cartel to wield monopoly prices on pharmaceutical products).

160. See Press Release, World Health Organization, WTO to Address Trade and Pharmaceuticals, *supra* note 30 (expressing that many WHO Member States are concerned that WTO-TRIPs Agreement could cause a negative impact on access to healthcare by creating a higher cost burden on essential drugs). See also Long & D'Amato, *The AIDS Drugs Controversy*, *supra* note 127, at 126 (noting increased protection will allow those companies to charge supra monopolistic prices in the developing world).

161. See Long & D'Amato, *The AIDS Drugs Controversy*, *supra* note 127, at 126.

162. These actions should be legitimized and supported by the fact that the WHO has highlighted the need to support countries in their quest to achieve access to affordable medicines as a key priority. See WORLD HEALTH REPORT 1999, *supra* note 19, at xii.

163. See Elliott, *supra* note 58, at A11. The TRIPs Agreement included safeguards to protect the interests of developing countries. See *id.* The first loophole, compulsory licenses found in Article 31 allows a country to override a patent, while the second loophole found

hole, grants the use of a patent through compulsory licenses.¹⁶⁴ A compulsory license allows the production of medicines by companies other than the patent holder in certain instances, such as public health emergencies or unfair pricing practices.¹⁶⁵

Article 6 of TRIPs is silent on the issue of parallel imports.¹⁶⁶ This silence allows developing countries to import medicines from countries other than the country of manufacture.¹⁶⁷ Parallel imports are "genuine goods or services imported by a reseller into a country without the authorization of the owner of the intellectual property right in that country."¹⁶⁸ The idea of parallel importing stems from the doctrine of exhaustion.¹⁶⁹ The doctrine states that a patentee is entitled to secure the

in Article 6, permits a country to determine its own policies relating to parallel imports. *See id.*

164. *See* TRIPs Agreement, *supra* note 7, art. 31. Article 31 provides for use of a patent without authorization of the right holder. *See id.* In pertinent part Article 31 provides:

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder . . . *This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use . . .*

Id. (emphasis added) (footnote omitted). *See* Boseley, *supra* note 147.

165. TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 164, art. 31(b) (providing that in the case of a national emergency or other extreme urgency compulsory licensees are available). *See* Médecins Sans Frontières, *Report to Thailand*, *supra* note 22.

166. TRIPs Agreement, *supra* note 7, art. 6. TRIPs remains silent on the issue of parallel imports as noted in Article 6, which reads in pertinent part:

For the purposes of dispute settlement under this Agreement . . . nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Id. Further, although Article 28(1)(a) of TRIPs confers an exclusive right of importation, this right is subject to the provisions of Article 6. *See* TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 155 art. 28 n.6. *See also* Barrett, *supra* note 9, at 918 n.22. Parallel imports were debated in the GATT negotiations. *Id.* However, the developed and developing countries maintained divergent opinions and thus no consensus was achieved. *See id.* As a consequence of this division, the TRIPs Agreement remains silent on the issue. *Id.*

167. *See* Médecins Sans Frontières, *Report to Thailand*, *supra* note 22.

168. Barrett, *supra* note 9, at 914 n.12 (quoting Claude E. Barfield & Mark A. Groombridge, *The Economic Case for Copyright Owner Control over Parallel Imports*, 1 J. WORLD INTELL. PROP. 903 (1998)). The subject of parallel imports is very intricate. *See* Barrett, *supra* note 9, for a detailed discussion.

169. The doctrine of exhaustion (DOE), also known as the doctrine of first sale, provides that an intellectual property owner has exclusive control over the first sale of an invention. *See* Barrett, *supra* note 9, at 911-12. Once the owner authorizes the release of

financial benefit of an invention only once. Once the patentee receives the benefit from the sale of a patented article, the patentee's rights to that product are exhausted.¹⁷⁰ The issue of parallel imports occurs, in part, as a reaction to a patent holder's practice of international price discrimination, charging higher or lower prices in different countries based on the cost that the market of a particular country can bear.¹⁷¹ For example, since the standard of living is considerably higher in the United States than a developing country, patentees are able to charge a price above that of the cost of the same item in a developing country.¹⁷² Many developing countries assert that parallel imports will serve to maintain a fair level of price competition in international markets.¹⁷³ Additionally, foreign

that item into the stream of commerce, all rights the owner previously had to control the item are exhausted. *Id.* at 912. Ideally, this right of first sale should provide an adequate financial incentive to ensure continued investment in the creative process, while still allowing purchasers and their successors in title to be free to use and resell the goods without seeking permission or paying a royalty. *Id.* at 912-13. Barrett provides a detailed discussion of three competing theories relating to the doctrine of exhaustion. *See id.* at 911 n.3, 914-16. The three competing theories are: 1. International exhaustion theory; 2. Modified international exhaustion theory; 3. Territorial/Domestic exhaustion theory. *See id.* Under the DOE, once a patent owner makes the first sale of a patented article, that article is no longer subject to the patent. *Id.* at 931. The first sale of a product exhausts the patent monopoly and removes any patent rights over subsequent sale of the product. *See id.* at 931, 937. However, a patentee's rights are not exhausted if the first sale of an invention is made without permission, which would preclude the patentee from receiving the initial benefit from the sale of that invention. *See id.* at 937

170. *See id.* at 912.

171. *See id.* at 958.

172. *See id.* Because of this price discrepancy, third parties may purchase a patented product in a developing country, at a low price and then resell the product in the United States placing it in direct competition with the United States patent. *See id.* Thus the parallel importer may be able to charge a lower price to United States consumers than the United States patentee. *Id.* Notably, the ability to resell a product in the United States at discriminatory price is not the only incentive to parallel importers. *See id.* at 958-59. Price differentials may reflect the higher cost a patent owner initially incurs through marketing a product. *See id.* at 959. For example, a parallel importer who resells goods in the United States, free rides on the patentee's expenditures such as advertising and marketing costs, which may have created the consumers' desire for a particular patented product. *See id.* In such a situation a parallel importer makes a substantial profit by charging a decreased price in the United States. *Id.* at 958.

173. *See Long & D'Amato, Does Intellectual Property Favor the "Have" Nations?*, *supra* note 49, at 135-36. Free riding is not inherently undesirable, and may be highly beneficial to the public, as long as it does not undermine the incentive to offer the product or service that is the subject of free riding. *Id.* The existence of some free riding by parallel imports is not, in itself, a reason to prohibit parallel importing. *Id.* A number of developing countries advocate for a rule of international exhaustion rule which would allow for parallel imports. *See Barrett, supra* note 9, at 951 n.136. *See also McCabe, supra* note 9, at 56 (noting that developing countries attain many benefits from corporations that copy patented goods).

courts reject the assertion that exhaustion relies on the availability and quality of patent protection in the country where the first sale occurs.¹⁷⁴ The European Court of Justice, ruled that a pharmaceutical proprietor exhausted its right to patent protection for a pharmaceutical product once it first placed the product on the market.¹⁷⁵ Accordingly, developing countries should not be held to standards higher than industrialized countries, such as the members of the European Union and should be allowed the freedom to permit parallel importation.

Now that developing countries have signed onto the Agreement, the safeguards of compulsory licensing and parallel importing, that had been placed in the Agreement to alleviate developing countries concerns, are not being enforced, and, in fact, developing countries are being pressured by Western governments to ban compulsory licensing and parallel imports.¹⁷⁶ In 1994, the United States Congress amended the United States' Patent Act to bring the United States into full compliance with TRIPs.¹⁷⁷ Since the TRIPs Agreement does not address parallel importation, Con-

174. See Barrett, *supra* note 9, at 966 n.177 (listing cases involving European Union countries and Japan).

175. See Case 187/80, Merck & Co. Inc. v. Stephar, 1981 E.C.R. 2063. The court ruled that parallel importation was permissible where:

[t]he proprietor of a patent for a medicinal preparation who sells the preparation in one Member State where patent protection exists, and then markets it himself in another Member State where there is no such protection, [prevents the proprietor] from availing himself of the right conferred by legislation of the first Member State to prevent the marketing in that state of the said preparation imported from the other Member State.

Id. Additionally the court stated: "That right of first placing a product on the market enables the inventor, by allowing him a monopoly in exploiting his product, to obtain a reward for his creative effort without, however, guaranteeing that he will obtain such a reward in all circumstances." *Id.*

176. See Médecins Sans Frontières, *Report to Thailand*, *supra* note 22. See also Wechkin, *supra* note 38, at 237 (commenting that due to pharmaceutical manufacturers desire to create an intellectual property regime the use of compulsory licensing provisions has been severely impeded); Elliott, *supra* note 58, at A11 (noting that the United States is making every effort to close the two loopholes).

177. See Uruguay Round Agreements Act, Pub. L. No. 103-465 §§ 532, 533, 108 Stat. 4809, 4983-90 (codified as amended at 35 U.S.C. § 154) (1994). As amended by this Act, the Patent Act § 154(a)(1) provides:

Every Patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

Id. Section 271(a), as amended, provides in part:

gress was not required to enact legislation against parallel imports in order to make the United States TRIPs compliant; however, the President's Statement of Administrative Action speaks to parallel importation.¹⁷⁸

The Statement conveys that United States law is already largely TRIPs compliant, and consequently, few changes to the law are required.¹⁷⁹ Inappropriately, the Statement also indicates that the TRIPs Agreement will have no effect on the law relating to parallel imports in the United States.¹⁸⁰ This statement does not coincide with the reality of the TRIPs Agreement which is silent on parallel imports, and thus cannot be seen as requiring a country to legislate against them. Clearly, this interpretation of parallel imports by the United States indicates that the United States is attempting to interpret all TRIPs provisions to their own benefit. In fact, TRIPs does not require a change in United States law with respect to parallel importation even though the President indicates in his statement that such legislation was required.¹⁸¹ Subsequently, the United States has threatened to sanction many countries that have applied such compulsory licenses or have practiced parallel importation.¹⁸²

[e]xcept as otherwise provided in this title, whoever without authority makes, uses, or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.

Id. See also Barrett, *supra* note 9, at 949-54.

178. See Message from the President of the United States Transmitting the Uruguay Round Trade Agreements, Text of Agreements Implementing Bill, Statement of Administrative Action and Required Supporting Statements, H.R. Doc. No. 316, 103d Cong., 2d Sess. (1994) [hereinafter Statement of Administrative Action], reprinted in 1994 U.S.C.A.N. 4040. See Barrett, *supra* note 9, at 952-53.

179. See Statement of Administrative Action, *supra* note 178, at 4280; Barrett, *supra* note 9, at 952.

180. See Statement of Administrative Action, *supra* note 178, at 4287; Barrett, *supra* note 9, at 952-53.

181. See Barrett, *supra* note 9, at 951-53.

182. See Fidler, *supra* note 19, at 211 (commenting that the United States government has put extreme economic and diplomatic pressure on South Africa and Thailand, "to turn them away from compulsory licensing."). See Wechkin, *supra* note 38, at 243. Not only have developing countries been subject to the threat of trade sanctions but countries such as New Zealand and Canada were also threatened by United States pressure. See *id.* at 256. As a result of this pressure New Zealand and Canada repealed their compulsory licensing provisions for pharmaceuticals. *Id.* See Médecins Sans Frontières, *Report to Thailand*, *supra* note 22. See also TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 166, art. 6; TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 164, art. 31. Notwithstanding the language of Article 6, some commentators have argued that other provisions of TRIPs or other Agreements with the GATT indirectly prohibit a policy of international exhaustion. See, e.g., Harvey E. Bale, *The Conflicts Between Parallel Trade and Product Access and Innovation: The Case for Pharmaceuticals*, 1 J. INT'L ECON. L. 637, 644, n.7 (1998) (relying on TRIPs art. 28). But see TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 155, art. 28 n.6 (defeating such arguments for

Having signed the Agreement, the Indian Parliament is required to amend its intellectual property laws to comply with the requirements set forth in TRIPs.¹⁸³ In the area of pharmaceutical patents, India and other developing countries have a transition period which will continue until January 1, 2005.¹⁸⁴ Additionally, TRIPs requires member countries to provide both product and process patent protection to patent owners, including the exclusive rights to make, use, offer for sale, sell, or import a patented product or process.¹⁸⁵ Signatories to TRIPs may exclude inventions from patentability if they do not protect public morality, "human, animal or plant life or health."¹⁸⁶ For example, these countries may exclude inventions in order to avoid serious prejudice to the environment.¹⁸⁷ However, because TRIPs does not authorize the exclusion of pharmaceutical products from patent protection, developing countries are required to extend protection to pharmaceuticals.¹⁸⁸

The TRIPs requirement, that governments provide both process and product patent protection to pharmaceuticals, will substantially increase the cost of pharmaceuticals, negatively affect the health of the poor and inhibit the government from providing real assistance to combat India's tremendous poverty.¹⁸⁹ Enforcing the TRIPs Agreement in the manner which industrialized countries demand will retard the positive growth India has experienced both in its labor force and health care of its people.

their failure to take into account footnote 6 to Article 28, indicating that Article 28 must be consistent with Article 6, which remains silent as to DOE).

183. See TRIPs Agreement, *supra* note 7, art. 1. In pertinent part Article 1 provides:

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their laws more extensive protection than is required by this agreement, provided that such protection does not contravene the provisions of this Agreement.

2. Members shall accord the treatment provided for in this Agreement to the nationals of other Members.

Id. (footnote omitted).

184. See TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 32, art. 65, art. 66 (providing developing country members a ten year transition period to implement intellectual property in pharmaceuticals).

185. See TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 155, art. 28.

186. See TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 155, art. 27(2); McCabe, *supra* note 9, at 50-51.

187. See TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 155, art. 27, 28.

188. See Weissman, *supra* note 10, at 1097-98 (noting Article 27 on its face makes the exclusion of pharmaceuticals from patent protection illegal); Koshy, *supra* note 25, at para. 29 (explaining that the exceptions provided for in Article 27 do not specifically include pharmaceuticals, therefore all TRIPs members must comply with Article 28 and extend product patent protection to pharmaceuticals).

189. See Tomar, *supra* note 14, at 583.

Full enforcement of the TRIPs Agreement negatively affects the government's ability to provide pharmaceutical products at affordable prices.¹⁹⁰ Furthermore, the TRIPs 'plus' attitude that developed countries such as the United States employ by increasing bilateral trade pressure, cannot be allowed to continue.¹⁹¹ At the 1998 World Health Assembly, the United States State Department representatives threatened to withdraw funding from the WHO when the organization aggressively supported improved access to patented medicines in developing countries.¹⁹² Despite the heavy handed attitude of the United States, continued support by the WHO, which received a mandate to monitor the public health consequences of international trade agreements, provides developing countries with some encouragement.¹⁹³

A. *Brand Name Innovators v. Generic Manufacturers*

To understand the issues, the competing agendas must be understood. Two groups comprise the pharmaceutical sector. These groups are 1) the innovators of new, brand name drugs and 2) the producers of generic or copied medicines.¹⁹⁴ The United States, as a world leader in pharmaceutical innovation, supports increased patent protection, while India, which relies predominately on copied generic medicines, does not.

1. The Innovators

In the United States, the innovators dominate generic producers.¹⁹⁵ The United States is a research-intensive country. Patent protection is given high priority due to the large amounts of money spent on research and development of new drugs.¹⁹⁶ An innovator is able to charge monopolistic prices and recoup expenditures via patent protection.¹⁹⁷ As a

190. *See id.* at 581.

191. TRIPs plus treatment occurs when developing countries are placed under additional pressure to implement changes in their laws that are above and beyond the TRIPs requirements. *See Médecins Sans Frontières, Report to Thailand, supra* note 22.

192. *See id.*

193. *See* WHA 52.19, *Revised Drug Strategy, supra* note 30; Médecins Sans Frontières, *Report to Thailand, supra* note 22.

194. Foster, *supra* note 26, at 296. *See generally*, Sanjiv Shankaran, *India: What Is the Generic Market All About*, BUSINESS LINE, Oct. 8, 2000, available at 2000 WL 27313161.

195. Foster, *supra* note 26, at 296.

196. *Id.* at 297.

197. *Id.* *See* James M. Silbermann, Comment, *The North American Free Trade Agreement's Effect of Pharmaceutical Patents: A Bitter Pill to Swallow or a Therapeutic Solution?*, 12 J. CONTEMP. HEALTH L. & POL'Y 607, 635 (1996) (explaining that a patent holder's limited monopoly on his invention results in higher product costs for the consumer). *See also* Shankaran, *supra* note 194 (noting that in the U.S. a product that is patented remains the monopoly of the patent owner).

result, the research-based pharmaceutical industry is most interested in protecting intellectual property, and is most upset when their sales are undercut by copiers abroad.¹⁹⁸ Innovators have 40% of sales in foreign markets, but lose approximately five billion dollars in revenue from sales to copiers.¹⁹⁹ The United States pharmaceutical industry has had a sustained campaign to focus its trade policy on ensuring expanded patent protection since the 1980s.²⁰⁰

2. The Generic Manufacturers

Generic manufacturers²⁰¹ in the United States have little influence in the political process.²⁰² Generic products in the United States can be sold at prices substantially cheaper than the prices patent holders receive for their product.²⁰³ However, generic manufacturers in the United States are distinguishable from those found in most developing countries.

In the United States, generic producers wait until a patent expires before making copies of a product, while in developing countries like India, producers ignore existing patents to develop copies of pharmaceuticals that are sold at much lower prices. Thus, even though Indian generic producers wield greater political influence,²⁰⁴ they are bound to the standards of TRIPs as dictated by industrialized nations.

In India, the generic manufacturers make copies of drugs regardless of whether the original patent is still valid.²⁰⁵ This occurs because Indian patent laws are extraordinarily weak and many product patents for pharmaceuticals are still unrecognized.²⁰⁶ In India, patents are only granted on the chemical process used to produce the drug, despite the fact that a new product can be created which is identical to the end prod-

198. See Foster, *supra* note 26, at 297-98.

199. *Id.* at 297-98.

200. See *id.* at 298. This campaign of the pharmaceutical industry has included large cash donations in the political arena. See *id.* Notably between 1981 and 1992, campaign donations to House and Senate candidates amounted to more than \$8.5 million. *Id.* These donations are provided equally to Democrats and to Republicans. *Id.* Thus, the pharmaceutical industry holds a great deal of influence over the government. See *id.* at 299. See Weissman, *supra* note 10, at 1070.

201. See Foster, *supra* note 26, at 301, for a detailed discussion on generic manufacturers.

202. *Id.* at 301. Notably 50% of prescriptions in United States are generic. *Id.* This occurs despite the fact that innovators outnumber generic companies. *Id.*

203. *Id.*

204. *Id.* at 306; Tomar, *supra* note 14, at 583.

205. See Foster, *supra* note 26, at 306; Shankaran, *supra* note 194.

206. See Foster, *supra* note 26, at 306; Shankaran, *supra* note 194.

uct.²⁰⁷ Thus, even when a patent is available, it poses no real obstacle to the creation of a generic copy as long as a different chemical process is used to obtain the same product.²⁰⁸

The TRIPs Agreement requires patents to be provided for both the process and the product of an invention.²⁰⁹ This requirement will force an increase in prices charged for products in developing countries, though industrialized nations will not be substantially affected.²¹⁰ As most industrialized countries already have patent systems in place, the TRIPs Agreement merely reinforces their current system without leading to price changes.²¹¹

B. *Viewpoint of the Western Pharmaceutical Companies, the United States & Industrialized Nations*

Western pharmaceutical companies view most generic producers of pharmaceuticals in developing countries as pirates who unfairly profit from their research.²¹² Recently, Harvey Bale, the Director General of the International Federation of Pharmaceutical Manufacturers Association, stated that the protection of patents, which are "the foundation of research and development," must be a priority for the industry.²¹³ Accordingly, during the Uruguay round of trade talks, the pharmaceutical industry, backed by the United States, successfully lobbied for stronger

207. See Foster, *supra* note 26, at 307; Shankaran, *supra* note 194; *Indian Company Advances Globally with Copy Drugs*, *supra* note 138.

208. "When TRIPs enters into full force in India an estimated 10,000 local pharmaceutical manufacturers which currently produce 70% of India's medicines, will collapse due to an inability to market their generic drugs." See Foster, *supra* note 26, at 307.

209. See TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 155, art. 28; Tomar, *supra* note 14, at 584.

210. See Foster, *supra* note 26, at 305.

211. See *id.*

212. See Michael M. Phillips & Mark Schoofs, *U.N.'s Annan Starts Aids Drug Campaign*, WALL ST. J., Mar. 2, 2001, at A7. Cf. McCabe, *supra* note 9, at 56 (stating that most industrialized countries assert that there is no economic benefit to pirating). See also Weissman, *supra* note 10, at 1088. Generic producers of pharmaceuticals are labeled pirates by the pharmaceutical industry and the U.S. government. *Id.* Countries with weak patent policies are denounced as harbors for such pirates. *Id.* Notably this use of a piracy metaphor changed what should have been a policy debate into an "absolutist moral drama." *Id.* Rather than addressing developing countries' concerns that they should be allowed to develop their own industries prior to adopting intellectual property protection, the use of the pirate metaphor marks such countries as supporting theft and thieves. See *id.* This attitude leaves no room for review of the merits of so-called piracy. *Id.*

213. Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6.

intellectual property protection to be incorporated into the Agreement.²¹⁴

The United States Trade Representative, which was a leading force in establishing the WTO,²¹⁵ has long backed the drug industry.²¹⁶ A 1998 statement by the USTR stated that the WTO helps the United States achieve its purpose of ensuring the prosperity and growth of the United States by providing it with the ability to sell its goods and services to consumers everywhere.²¹⁷ Additionally, it stated that the United States sought to secure maximum benefits for American businesses and workers by obtaining a strong, binding, and expeditious dispute settlement process through the WTO.²¹⁸ Notably, during the United States 2000 Presidential Campaign, the drug industry spent an unprecedented \$80 million to help elect George W. Bush and ensure that the government stood behind the industry.²¹⁹ The United States government has pressed all countries not only to comply with TRIPs, but also to accelerate implementation of these obligations.²²⁰

214. See Weissman, *supra* note 10, at 1084. The United States call for world-wide adoption of U.S. style patent law, was largely influenced by its pharmaceutical industry. *Id.* In fact, the Intellectual Property Committee, claimed to have acted in a "key advisory role" at the request of the USTR, in the development of the government's proposal presented in the GATT-TRIPs negotiations. *Id.* See also America and the World Trade Organization, United States Trade Representative, *supra* note 86, at 5 (admitting that the United States sought and obtained, in the WTO, agreements on intellectual property, in order to open U.S. markets and lower barriers to U.S. exports); Elliott, *supra* note 58, at A11 (establishing that the pharmaceutical industry in the U.S. was the strongest influence in pushing for a 20 year patent term).

215. America and the World Trade Organization, United States Trade Representative, *supra* note 86, at 2.

216. Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6. See also Elliott, *supra* note 58, at A11 (asserting that the United States government does the "dirty work" for the pharmaceutical companies).

217. America and the World Trade Organization, United States Trade Representative, *supra* note 86, at 2.

218. *Id.* at 5.

219. Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6. See also Tina Rosenberg, *Look At Brazil*, N.Y. TIMES, Jan. 28, 2001, New York Times Magazine (recognizing that the pharmaceutical manufactures have long financed both political parties in the United States).

220. See The United States Trade Representative, *The Work of the USTR-Intellectual Property*, *supra* note 61 (noting that although developing countries have transition periods the U.S. is pushing these countries to meet the requirements of TRIPs).

1. Arguments Supporting Enhanced Patent Protection of Pharmaceuticals

The industrialized countries and the pharmaceutical industry assert various reasons that explain why developing countries should implement strong patent systems.²²¹

a. Development of New Pharmaceutical Products

Industrialized nations assert that pharmaceutical corporations need patent protection for pharmaceutical products in order to recover research and development costs, which will in turn lead to the development of new innovations.²²² The development of new drugs is expensive, imposes high risks, and is a time consuming process. Without patent protection, inventors would have little incentive to develop new drugs.²²³ If a product is easily copied and then sold at lower prices, an inventor would not be able to recoup costs and would be unlikely to take the time, money or risks associated with developing a new product.²²⁴ As such, a country with weak patent laws creates a disincentive for inventors and leads to a decline in research and development for new medicines.²²⁵ However, according to pharmaceutical companies, a country with patent protection will reap the benefits of increased foreign investment, which will lead to the research, development and production of new pharmaceuticals.²²⁶

221. See Weissman, *supra* note 10, at 1086 (noting that the industry argued that enhanced intellectual property protection would foster economic developments in third world countries as well as encourage foreign and domestic investment, and technology transfer).

222. See Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM I.P., MEDIA & ENT. L.J. 185, 187 (1999); Peterson, *supra* note 40, at 278.

223. Barfield & Groombridge, *supra* note 222, at 208; Fisch, *supra* note 68, at 308, 312. See also Mike Moore, WTO Director General, *Yes, Drugs for the Poor—and Patents as Well*, M2 PRESSWIRE, Feb. 26, 2001 (asserting that because the cost of the development of a new drug is approximately \$500 million, without patents which provide rewards to the inventors who risk millions on research the development, new drugs to treat diseases would lapse).

224. See Barfield & Groombridge, *supra* note 222, at 215; Peterson, *supra* note 40, at 278; Vicente, *supra* note 6, at 1121.

225. See Barfield & Groombridge, *supra* note 222.

226. See Adelman & Baldia, *supra* note 14, at 530 (contending that patent systems will ensure that developing countries such as India develop a strong R&D sector, which will lead to the creation of new drugs). Cf. Christopher S. Mayer, Notes & Comments, *The Brazilian Pharmaceutical Industry Goes Walking From Ipanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Investment?*, 12 TEMP. INT'L & COMP. L.J. 377, 394 (1998) (outlining potential benefits that intellectual property reforms will provide to developing countries).

b. Increased Transfer of Technology

Developing countries will benefit from increased patent protection as they will experience increased transfer of pharmaceutical technology and capital investment necessary for economic growth and development.²²⁷ A country with a weak patent system slows its own economic growth by essentially creating a trade barrier against the import of new pharmaceutical products.²²⁸ This leads to diminished transfer of technology and production capacity.²²⁹

c. Increased Investment to Stimulate Domestic R&D

Patent protection encourages the development of a country's domestic pharmaceutical industry because domestic pharmaceutical companies will have to invest in research and development if they are prohibited from pirating patented drugs.²³⁰ Increased patent protection will also lead to in-country retention of scientists and other innovators who might have chosen to leave a country with weak patent law in order to gain protection for their innovation and ideas.²³¹ Additionally, developing countries will gain many benefits such as increased employment and education. These benefits will be derived from the ability to educate, recruit, and hire scientists to work a patent, and recruit and hire lawyers to protect pharmaceutical patent rights.²³²

d. Ensures the Quality of Pharmaceutical Products

A country that requires patent protection for pharmaceuticals ensures the quality and safety of the medicines produced, and reduces the risk of inferior quality or counterfeit drugs which create health risks.²³³ Countries with weak patent systems often allow the introduction of unsafe drugs into the marketplace because there are no checks on the product and there is little fear of liability.²³⁴

227. See Peterson, *supra* note 40, at 278, 281; Mayer, *supra* note 226, at 394; David Benjamin Snyder, Comment, *South Africa's Medicines and Related Substances Control Amendment Act: A Spoonful of Sugar or a Bitter Pill to Swallow?*, 18 *DICK. J. INT'L L.* 175, 189 (1999); Su, *supra* note 5, at 204.

228. See Barfield & Groombridge, *supra* note 222, at 219 (noting that an inventor will not want to export their product to a country that would quickly copy and sell a generic version).

229. *Id.* at 221.

230. See Adelman & Baldia, *supra* note 14, at 530; Mayer, *supra* note 226, at 399.

231. See Adelman & Baldia, *supra* note 14, at 533; Su, *supra* note 5, at 204.

232. See Tomar, *supra* note 14, at 602.

233. See Barfield & Groombridge, *supra* note 222, at 254; Peterson, *supra* note 40, at 279; Tomar, *supra* note 14, at 584; Vicente, *supra* note 6, at 1125.

234. See Tomar, *supra* note 14, at 584.

e. Incentive for Pharmaceutical Manufacturers to Discount Medicines for Developing Countries

Industrialized nations assert that in developing countries such as India, the limited purchasing power of the people will act as a check on price increases.²³⁵ Additionally, if a country provides patent protection to pharmaceuticals, United States manufacturers and trade officials assert that new drugs would be more effectively distributed to developing nations.²³⁶ If a country protects patents, pharmaceutical companies would be willing to sell essential medicines to developing countries at reduced prices.²³⁷ This assertion is supported by the fact that pharmaceutical companies have dropped the price of certain AIDS drugs by fifty to seventy-five percent for developing countries.²³⁸

C. Viewpoint of India and Developing Countries

The physical and economic burdens created by disease affect people in the developing world more significantly than those in developed countries.²³⁹ The health gap that exists between developing and developed countries is a predominant reason that developing countries, such as India, have fought the implementation of patents on pharmaceuticals.²⁴⁰ Because of the Indian drug consumers' reliance on the availability of generic drugs, the Indian consumers, unlike their American counterparts, took an active role in the fight against TRIPs.²⁴¹ The Indian drug consumers' primary concern over patent protection has been the price increases they will face.²⁴² Keeping the price of pharmaceuticals down is of the utmost importance, considering that a majority of India's one billion plus people live below the poverty line.²⁴³ India has over one million

235. See Adelman & Baldia, *supra* note 14, at 531. See also Koshy, *supra* note 25, at para. 47 (asserting that since a majority of the people could not afford higher pharmaceutical prices their limited purchasing power will act as a self-regulating mechanism forcing manufacturers to either have a low volume in sales or to keep costs low).

236. Cf. Snyder, *supra* note 227, at 189 (pointing out potential benefits to the South African pharmaceutical patent system).

237. See Barfield & Groombridge, *supra* note 222, at 195.

238. *Id.* at 251.

239. See Press Release, World Health Organization, WTO to Address Trade and Pharmaceuticals *supra* note 30. The Director of Essential Drug and Other Medicines at WHO, stated that the inequities between developed and developing countries are striking. Distressingly, in many of the developing countries one year's HIV treatment would consume 30 years of income if purchased. See also Fidler, *supra* note 19, at 191.

240. See Fidler, *supra* note 19, at 191.

241. See Foster, *supra* note 26, at 308.

242. *Id.* at 309.

243. See Office of the Registrar General of India, *supra* note 23 (stating that the population of India on March 1, 2001 was 1,012,395,934); Foster, *supra* note 26, at 309.

HIV positive individuals, many of them poor and dependent on pharmaceuticals.²⁴⁴ Price increases in drugs are effectively life-threatening, particularly as many of those drugs are currently sold at prices up to four times less than the price charged in the West.²⁴⁵

India was a leader in fighting the implementation of an intellectual property agreement within the GATT and was a strong voice in asserting the need for a lengthy transition period for developing countries.²⁴⁶ The Indian economy greatly improved by 1995, allowing India an improved bargaining with the United States, a factor which explains why it has been able to delay the implementation of the TRIPs mandated legislation.²⁴⁷

The American Government stands accused of conspiring to help supporters in the rich and powerful American pharmaceutical industry at the expense of millions of people who are dying of AIDS in developing countries.²⁴⁸ Additionally, pharmaceutical producers from developing countries argue that the real reason drug firms from developed countries want intellectual property law changes is to maximize their profits. This appears to be particularly true considering that during their own process of industrialization, industrialized nations extensively used reverse engineering and methods of imitating innovative products.²⁴⁹ Only after the industrialized countries had reaped the benefits of non-protectionist policies to their fullest extent did they close the door to developing countries, thereby restricting them and making technological progress significantly more difficult.²⁵⁰

244. Foster, *supra* note 26, at 309.

245. *See id.* at 310.

246. *See id.* at 311-12. India ultimately signed the GATT, including TRIPs, largely due to their economic concerns at the time. *See id.* at 314. Prime Minister Rao admittedly signed the Agreement knowing that he did not have popular support for the intellectual property provisions. *Id.*

247. *See id.* at 318. The Indian economy reached a turning point after a currency infusion from the International Monetary Fund and measures implemented to ensure austerity. *Id.* "[B]y 1995-96 the fiscal deficit had been lowered from 8.4% in 1990-91 to 5.6%, while external debt service payments" in fact "declined from 35.3% to 26.6%." *Id.* Beneficially, to India, during that period the economic growth rates experienced an astounding recovery of 5.3%. *Id.* Additionally in 1994, India developed nuclear technology in the form of an Intermediate range Ballistic Missile and thus the United States became more amenable to India in order to induce it to join the Nuclear Non-Proliferation Treaty. *See id.*

248. Boseley, *supra* note 147.

249. *See Harbaksh Singh Nanda, India's Commerce Minister Scores Effects of WTO TRIPs Accord*, Bureau of National Affairs, Inc., Washington D.C. (July 17, 2000), at <http://wtowatch.org/news/index.cfm?ID=2135> (on file with author).

250. *See Mossinghoff, supra* note 12, at 592 (indicating that, through the 1952 codification of the U.S. Patent statute into Title 35 of the U.S. Code, the United States Congress reversed many of the Supreme Court's anti-patent rulings); Weissman, *supra* note 10, at

The fears of developing countries are not unfounded.²⁵¹ Considering that many developing countries are impoverished and have limited funds, the need to acquire essential medicines supercedes a willingness to grant patents that could prohibit access to pharmaceutical technology because of monopolistic prices.²⁵²

1. Concerns of Developing Countries Regarding Patent Protection of Pharmaceuticals

Developing countries reject many of the arguments put forth by developed nations which assert that patent protection of pharmaceuticals will benefit developing countries. Those arguments fail to consider the diverse needs of developing countries and the negative impact that patent protection will have on the development of those countries.

a. Autonomy, Sovereignty and Cultural Beliefs Undermined

Many developing countries are concerned that with the imposition of Westernized intellectual property rights comes the return of a colonizing factor which will result in the loss of autonomy and a developing country's sovereign right to determine its own laws.²⁵³ Such standards will force a developing country into continued technological dependence on

1119 ("Indeed, it was through imitation that virtually every industrialized country built up its technological capacity"). See, e.g., Sherwood, *supra* note 12, at 501. Notably, prior to 1970, decisions rendered by the United States Supreme Court contained statements that patents are monopolies. *Id.* In recent years, the Court has shifted its condemnation and instead refers to patents as offering "rent seeking opportunities." *Id.* See also Su, *supra* note 5, at 200 (discussing the doctrine of uneven development in which the developed countries industrialized at the expense of developing countries and have not since allowed developing countries the opportunity to advance); Nanda, *supra* note 249 (voicing concerns of Indian Commerce Minister Maran).

251. See U.N. Conference on Trade & Dev., The TRIPs Agreement and Developing Countries, 25 U.N. Doc. UNCTAD/ITE/1, U.N. Sales No. 96 II.D.10 (1996) (observing that most of the immediate benefits of TRIPs will accrue to the industrialized countries).

252. Cf. McCabe, *supra* note 9, at 52-53. Many developing countries argue that patent protection allows industrialized countries to stay ahead in the technological sector. *Id.* This ensures that transfer of technology is denied to the developing countries, which might use such a transfer to begin their own research and development process. *Id.* at 53. This in turn affects a developing country's ability to develop self-sustaining pharmaceutical industry. *Id.* at 53. Cf. Wechkin, *supra* note 38, at 237 (noting that some argue the high prices which result from the monopolistic power of patents will result in a reduction of availability of essential medicines).

253. See Tomar, *supra* note 14, at 583 (noting the fear that India may be returned to dependent nation status if it complies with the TRIPs Agreement); Smith, *supra* note 27, at 214, 234 (asserting that the standards of intellectual property protection appear to be dictated from the West); Vicente, *supra* note 6, at 1127 (arguing that the drug industry's arguments supporting enhanced intellectual property are one sided and prevent the natural expression of national sovereignty).

industrialized countries, prevent them from acting as participants, and deter development.²⁵⁴ Developing nations assert that intellectual property protection should be established only if it is consistent with their own needs, not those of multinational corporations or the industrialized countries.²⁵⁵ Thus, in the case of pharmaceuticals, patent protection is viewed as only in the self-interest of the developed nations who wish to protect their profits.²⁵⁶ Developed countries advance increased intellectual property protection because they will receive the primary benefits through their exports.²⁵⁷

This view is fostered by the fact that Western-imposed views on intellectual property rights are inconsistent with the cultural belief that knowledge is viewed as the common heritage of mankind, found in many developing countries.²⁵⁸

b. Research and Development: New Drugs for the Affluent, Infectious Diseases for the Poor

The major pharmaceutical companies, backed by industrialized nations, argue that patent protection for pharmaceuticals allows their companies to invest in the research and development of new drugs to treat infectious diseases found predominately in developing countries.²⁵⁹ Does R&D depend on twenty year patent monopolies to charge exorbitant prices—not

254. See Smith, *supra* note 27, at 231. Cf. Todd M. Rowe, Comment, *Global Technology Protection, Moving Past the Treaty*, 4 MARQ. INTELL. PROP. L. REV. 107, 1123 (2000) (explaining that India is a country "rich in technical potential" but that any technological progress must encompass the unique cultural perspective, found in many developing nations, which take a community approach to property).

255. See Sarma, *supra* note 4, at 135. See also Rowe, *supra* note 254, at 111 (asserting developing countries should not be pressured to adopt Western intellectual property systems).

256. Cf. Su, *supra* note 5, at 205 (speaking broadly to the impact of intellectual property).

257. See McCabe, *supra* note 9, at 53-54. Intellectual property provides the most benefits to countries with market based economies which can rely on private capital and open trade, a system which many developing countries do not have. *Id.* at 54. See Peterson, *supra* note 40, at 280.

258. See D'Amato & Long, *Common Heritage of Mankind*, *supra* note 40, at 61. See generally Theresa Beeby Lewis, Comment, *Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries*, 30 INT'L. LAW. 835, 839 (1996) (describing the belief held by developing countries that knowledge and thus intellectual property is common property); Rowe, *supra* note 254, at 123 (commenting on developing countries community approach to development); Smith, *supra* note 27, at 224-28 (illustrating that there exists a misalignment between developing and developed countries as to the cultural and social attitude on the sharing of intellectual property).

259. See Adelman & Baldia, *supra* note 14, at 530; Vicente, *supra* note 6, at 1132; Elliott, *supra* note 58, at A11.

likely.²⁶⁰ None of the pharmaceutical companies really depend on achieving profits in developing countries, which generally only account for a minimal percentage of drug sales world-wide.²⁶¹ This argument fails to acknowledge that, in fact, of the money used towards R&D, only ten percent is used to develop drugs that account for ninety percent of the world's diseases in developing countries.²⁶² Ninety percent of R&D, is actually spent on providing treatments for the affluent, such as diet drugs, or impotency drugs such as Viagra.²⁶³ Because infectious diseases are found predominately in developing countries, they have not been a priority for the pharmaceutical industry.²⁶⁴ The industry already focuses primarily on developing drugs for the consumers in rich industrialized countries rather than essential drugs.²⁶⁵ Treatment for diseases such as tuberculosis, malaria,²⁶⁶ and AIDS, those common in developing countries, would continue to be ignored.²⁶⁷

The industry asserts that they lose too much money in countries that do not provide patent protection because their drugs are pirated.²⁶⁸ This argument is also lacking. It fails to consider the fact that prior to the TRIPs Agreement, the profit margins of the pharmaceutical corporations were high enough to foster R&D, even in the face of generic copies in developing countries.²⁶⁹ These claims of piracy are exaggerated and the losses suffered by the major pharmaceutical corporations are overstated.²⁷⁰ Because of the high cost of patented pharmaceuticals, consumers in developing countries would never have been able to purchase the patented

260. Rosenberg, *supra* note 219.

261. *See id.* For example Africa only accounts for 1.3% of pharmaceutical sales. *Id.* Additionally, even if the pharmaceutical companies sold their drugs at substantial discounts, they would still profit. *Id.*

262. *See Elliott, supra* note 58, at A11.

263. *Id.*

264. *See Vicente, supra* note 6, at 1132. *See generally Elliott, supra* note 58, at A11.

265. *See Vicente, supra* note 6, at 1132.

266. WORLD HEALTH REPORT 1999, *supra* note 19, at xii. This report recognized that malaria and underdevelopment are closely intertwined. *Id.* Over 40% of the world's population live where there is a risk of malaria a disease which imposes premature death and suffering and causes severe economic retardation. *Id.* Malaria flourishes in situations of social and environmental crisis, weak health systems and disadvantaged communities. *Id.*

267. *See id.* at 13-17; *Optimism About Malaria Vaccine Grows*, USA TODAY, (Dec. 3, 1999), available at <http://www.usatoday.com/life/health/general/Ihgen190.htm> (last visited Dec. 3, 1999).

268. Vicente, *supra* note 6, at 1129.

269. *See Elliott, supra* note 58, at A11. Additionally, much of the money that the pharmaceutical companies claim goes to R&D is also spent on marketing drugs. *See id.*

270. *See Vicente, supra* note 6, at 1129.

versions. Thus, the companies cannot be losing sales that would never have been made.²⁷¹

By allowing the production of generic medicines through compulsory licenses, a developing country is enabled to stimulate economic development while gaining access to essential medicines.²⁷² A local industry that exists without patent protection will better serve national health needs in poor countries than high cost brand name pharmaceuticals.²⁷³

c. Medication for the Nation: Access to Essential Medicines Denied

Developing countries cannot afford the cost of maintaining a strong intellectual property regime.²⁷⁴ The continued push of patent protection on pharmaceuticals places an unreasonable burden on the ability of developing countries to access essential drugs.²⁷⁵ In light of this it is in the public interest to allow an exception to intellectual property protection in the area of pharmaceuticals for developing countries.²⁷⁶ As developing countries have limited resources, it is inappropriate to apply them to the

271. See *id.* at 1130.

272. Cf. McCabe, *supra* note 9, at 56. McCabe explains that a developing country needs to be able to stimulate economic growth before a country can afford to implement a strong intellectual property system. *Id.* Additionally, he notes that developing countries' economic growth is actually fueled by pirating patented drugs. *Id.* Consequently, if developing countries are unable to maintain generic industries that copy pirated drugs, they will realize a reduction in domestic output and an increase in unemployment rates. *Id.* Generic/pirate companies will likely choose to establish their business in countries without strict intellectual property protection. *Id.* This will in fact hurt a developing country rather than provide the benefits espoused by developed countries. *Id.* See also Wechkin, *supra* note 38, at 240 (noting that compulsory licensing provides a way in which developing countries can simultaneously develop medicines and a pharmaceutical manufacturing industry without the prohibitive costs associated with independent research and development).

273. See Vicente, *supra* note 6, at 1132.

274. See McCabe, *supra* note 9, at 54 (discussing the fact that most developing countries do not have ready access to private capital and thus a strong intellectual property regime creates an increased financial burden on developing countries). Cf. Lewis, *supra* note 258, at 835 (fearing price increases and loss of control over technological development, developing countries view the grant of intellectual property with skepticism); Rowe, *supra* note 254, at 131 (asserting that intellectual property protections modeled on the United States system would be useless for developing nations which do not have sufficient resources to provide their citizens with basic necessities such as health care, education, food and clothing).

275. WORLD HEALTH REPORT 1999, *supra* note 19, at 13. See Fidler, *supra* note 19, at 210.

276. See Vicente, *supra* note 6, at 1133-34 (asserting that an exception to patent policy in the area of pharmaceuticals for developing countries' health interests should be allowed in the public interest). Cf. Smith, *supra* note 27, at 248 (indicating that public interest exceptions have been allowed under TRIPs).

protection of monopolistic foreign owned pharmaceutical patents, as the health needs of the people should take precedence.²⁷⁷ Industrialized countries have vast resources and thus do not experience the same financial strain that a developing country would experience by having to implement an elaborate patent system.²⁷⁸

More importantly, as it relates to patenting of pharmaceuticals, medicines will become unaffordable to the general populace and thus patent protection acts to prohibit widespread access.²⁷⁹ For developing countries, providing patent protection to drugs will provide little benefit to their poverty stricken citizens.²⁸⁰ Patents provide monopolies that result in high drug prices and high health care costs, which is an unfair burden to impose on poor developing countries.²⁸¹

Recently, the pharmaceutical companies have begun to offer their brand name drugs at reduced prices, however, the drugs produced at cheaper prices are still unaffordable to the world's poor and more expensive than the generic alternatives.²⁸²

d. Patent Protection for Pharmaceuticals Will Cause the Death of the National Pharmaceutical Industry to the Benefit of Multinational Corporations

In the early 1950s when India was still guided by a British style patent system, eighty to ninety percent of Indian patents were owned by non-Indians and less than ten percent of patents were actually worked in India.²⁸³ Since India implemented weaker patent laws, Indian companies

277. Cf. McCabe, *supra* note 9, at 55 (speaking broadly on intellectual property); Vicente, *supra* note 6, at 1133 (discussing monopoly pricing as a factor affecting public health); Rowe, *supra* note 254, at 133 (emphasizing that requiring developing nations to provide patent protection to drugs would be absurd as their would be minimal benefits to their poverty-stricken populations).

278. See Rowe, *supra* note 254, at 133. See, e.g., Vicente, *supra* note 6, at 1132. Even in developed countries when patent protection is imposed the price of medicines increases. *Id.* In Canada, the cost of pharmaceuticals increased by fifty-three percent, five years after the government adopted patent laws consistent with United States demands. *Id.* For a developing country such a scenario is potentially disastrous.

279. See Tomar, *supra* note 14, at 601. Tomar notes that patent protection will decrease drugs available and increase prices because the cost associated with research and development will fall upon consumers. See *id.* In developing countries such as India, the poor people will be unable to afford them. See *id.* See also Lewis, *supra* note 258, at 839 (expressing that debate over the patent protection of pharmaceuticals involves social considerations such as the desire to keep health care costs low). Cf. Koshy, *supra* note 25, at para. 36 (discussing the fears of critics of patent protection on pharmaceuticals).

280. Rowe, *supra* note 254, at 133.

281. See Vicente, *supra* note 6, at 1118; Wechkin, *supra* note 38, at 237.

282. See Elliott, *supra* note 58, at A11.

283. Adelman & Baldia, *supra* note 14, at 518.

manufacture between seventy and eighty-five percent of drugs in the domestic market.²⁸⁴ Weak patent laws have allowed India to enter pharmaceutical markets, reversing the trend of the past where large foreign multinational companies, owned by Europeans and the United States, dominated India's pharmaceutical industry.²⁸⁵

If patent protection is provided to pharmaceuticals, patents will be held by foreigners and not worked in the developing country, thus giving multinational corporations a controlled monopoly.²⁸⁶ Jobs will be displaced in the national drug sector.²⁸⁷ Developing nations such as Brazil, India and Thailand, which have developed the ability to produce generic copies of brand name drugs at lower prices, will not only see a drop in affordable medicines, they will see a large job creating local industry disappear.²⁸⁸

e. The Promised Transfer of Technology and Stimulation of Domestic Research and Development Will Never Be Realized

Increased intellectual property protection will cause the economic gap between developed and developing countries to grow wider.²⁸⁹ A tighter regulated patent system prevents a transfer of technology and denies developing countries the opportunity to create their own research and development in the pharmaceutical industry.²⁹⁰ The local pharmaceutical

284. See *id.* at 527; Koshy, *supra* note 25, at para. 23.

285. See Tomar, *supra* note 14, at 582-83.

286. See Adelman & Baldia, *supra* note 14, at 530 (summarizing the Indian fears surrounding the implementation of pharmaceutical patents); Tomar, *supra* note 14, at 582 (remarking that this is particularly troubling as developing nations already are behind developed nations in the creation of inventions); Koshy, *supra* note 25, at para. 37 (discussing the concern that multinational corporations will lead to the end of the domestic pharmaceutical market).

287. See Adelman & Baldia, *supra* note 14, at 530 (discussing the Indian fear regarding the adoption of patents for pharmaceuticals). See also Mayer, *supra* note 226, at 394 (providing that developing countries would experience loss of firms that had copied drugs under a weakened patent law system).

288. Cf. Adelman & Baldia, *supra* note 14, at 530 (speaking specifically about concerns of job displacement in India with the implementation of pharmaceutical patents); Mayer, *supra* note 226, at 394.

289. See Rowe, *supra* note 254, at 136.

290. See McCabe, *supra* note 9, at 53. See also Peterson, *supra* note 40, at 280 (noting that the vast majority of patents are issued to inventors from developed countries); Lewis, *supra* note 258, at 839 (asserting that technology transfer is more important to developing countries than encouraging innovation); Rowe, *supra* note 254, at 135 (finding that an intellectual property system based on a western model is not justified by the minimal technological advancement that developing nations would receive). Cf. Su, *supra* note 5, at 205 (noting that intellectual property protection mechanisms act as an obstacle to the transfer of technology and impedes development).

industry, which produces generic drugs at lower prices than patent owners, creates a demand which stimulates domestic production, and in turn leads to competition and economic development within the developing country.²⁹¹ Notably though, most industrialized, technologically advanced countries now maintain and advance strong intellectual property protection, "virtually every industrialized country adopted strong patent laws [only] after developing their technological infrastructure, in significant part through copying strategies."²⁹² Currently, developing countries that have not imposed stringent patent system have proven to be more innovative in the development of their technology capability, than developing countries that have strictly applied patent systems.²⁹³ A patent system cannot provide what most developing countries need: a science or technology infrastructure as provided through a system of advanced education and research.²⁹⁴ Rather than rely on industrialized countries for technology transfer, developing countries must be allowed to undertake their own research and development initiatives to stimulate their own domestic growth.

D. *A New Precedent: A South African Victory for All Developing Countries*

South Africa became the subject of world attention shortly after it enacted the Medicines and Related Substances Control Amendment Act, No.90 of 1997.²⁹⁵ The legislation, signed by President Nelson Mandela, authorized the use of compulsory licensing of generic medicines and the purchase of more affordable medicines through parallel imports, in an

291. See Peterson, *supra* note 40, at 280. See also Weissman, *supra* note 10, at 1119 (noting that weak or non-existent patent protection on pharmaceuticals has allowed India, Argentina and Turkey to develop flourishing pharmaceutical industries).

292. Weissman, *supra* note 10, at 1119 (footnote omitted).

293. See *id.* at 1123.

294. See *id.* at 1124.

295. Médecins Sans Frontières, *Background Information: South Africa Medicines Law (Act 90) and Access to Medicines*, [hereinafter Médecins Sans Frontières, *Background Information: South Africa Medicines Law*], at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author). See Martine Bulard, *Apartheid of Pharmacology*, LE MONDE DIPLOMATIQUE, Jan. 2000, available at <http://www.accessmed-msf.org> (last visited Feb. 26, 2001) (on file with author); *Letter from MSF to Commissioner Pascal Lamy re: South Africa*, (Mar. 5, 2001) (written by Morten Rostrop, President of Médecins Sans Frontières International Council) [hereinafter *Letter from MSF to Commissioner Pascal Lamy*], available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author). See also Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6 (explaining that the South African Ministry of Health asserts that the legislation reflects the governments' assertion that equal access to health care is a constitutionally protected right).

attempt to find a solution to the lack of access to affordable medicines.²⁹⁶ Because of the high cost of drugs, very few South Africans have access to the same drugs that greatly extend lives in the developed world.²⁹⁷ The AIDS epidemic has created a serious health concern.²⁹⁸ In Africa twenty-two million people are infected with the AIDS virus, comprising 65% of all people infected world wide.²⁹⁹ In South Africa more than 4.3

296. Steve Sternberg, *Victims Lost in Battle Over Drug Patents*, USA TODAY, Sept. 15, 1999. See Long & D'Amato, *The AIDS Drugs Controversy*, *supra* note 127, at 126; Paul Benkimoun, *WTO's Impact on Third World Health Eyed: AIDS, Seattle, and the Health Exception*, WORLD NEWS CONNECTION/WORLD REPORTER, Dec. 1, 1999, available at <http://www.accessmed-msf.org> (last visited Feb. 26, 2001) (on file with author); Rosenberg, *supra* note 219; Ed Vulliamy, *How Drug Giants Let Millions Die of AIDS*, THE OBSERVER, Dec. 19, 1999, available at <http://www.accessmed-msf.org> (last visited Feb. 26, 2001) (on file with author); *Open Letter to Commissioner Pascal Lamy (Trade)*, European Commission, (Feb. 12, 2001) (written by Morten Rostrup, President of Médecins Sans Frontières International Council), [hereinafter *Open Letter to Commissioner Pascal Lamy*], available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author); *Open Letter to Members of the European Parliament re: South Africa Medicines Act* (Feb. 26, 2001) (prepared by Médecins Sans Frontières), [hereinafter *Open Letter to Members of the European Parliament*], available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author); *Open Letter to 39 Pharmaceutical Companies re: South Africa Medicines Act* (Feb. 22, 2001) (prepared by Médecins Sans Frontières & Oxfam-Great Britain) [hereinafter *Open Letter to 39 Pharmaceutical Companies*], available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author); Press Release, Médecins Sans Frontières, Drop the Case! Support the Struggle for Medicines in South Africa (Mar. 8, 2001) [hereinafter Press Release, Médecins Sans Frontières, Drop the Case!], available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author). See also Médecins Sans Frontières, *Background Information: South Africa Medicines Law*, *supra* note 295. The clause of the Act which caused the most debate was Section 15C. *Id.* It permits the parallel importation of medicines, which would allow South Africa to shop around for the lowest world price on patented products. *Id.* This would mean that if a patent holder sells a product for a lower price in India than in South Africa, the cheaper drugs sold in India could be imported to South Africa. *Id.* Additionally Section 15C allows the Minister of Health to override patent protection by issuing compulsory licenses in order to facilitate access to necessary medicines. *Id.* This allows the use of a patented product without the consent of the patent holder. *Id.* The TRIPs Agreement allows in Article 31 for compulsory licensing in the case of national emergencies or to remedy anti-competitive practices. *Id.* See generally Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6. Parallel importing allows an importing country to buy drugs from the cheapest available source whether the original patent holder gives permission or not. *Id.* Compulsory licensing allows a government to license local manufacturers to produce copies of pharmaceuticals, to be sold at cheap prices, whose patents are held by foreign corporations.

297. *40 Drug Companies Take Government to High Court over Generic Drugs Plan*, AFRICAN NEWS SERVICE, Mar. 2, 2001.

298. See Snyder, *supra* note 227, at 176 (noting that in addition to the AIDS cases South Africans also fall victims to other diseases such as malaria and tuberculosis).

299. See Bulard, *supra* note 295. The devastating fact is that AIDS related deaths in Africa will exceed the 20 million victims of the European plague. *Id.* See Rosenberg, *supra*

million people have HIV, which is more than any other country in the world.³⁰⁰ The proportion of the population that can afford the high priced medicine is extremely small, and the vast majority of people infected with AIDS cannot afford treatments.³⁰¹ The use of generic drugs over brand name drugs has resulted in substantially lower prices, thus increasing access.³⁰² Many developing countries and non-governmental organizations, such as Médecins Sans Frontières (MSF) and Oxfam, supported South Africa's legislation as TRIPs compliant, in accordance with the provisions on parallel imports and compulsory licenses.³⁰³ The TRIPs Agreement, by remaining silent on parallel imports, in Article 6, and by authorizing compulsory licenses under certain conditions for health emergencies, in Article 31, allows for countries to protect public health concerns.³⁰⁴

note 219; *Companies Agree to Cut Prices of HIV Drugs in Poor Nations*, MEDICAL INDUSTRY TODAY, May 12, 2000; Steve Sternberg, *Activists Discount Big Drugmakers' Gifts*, USA TODAY, Jul. 11, 2000.

300. Médecins Sans Frontières, *Background Information: South Africa Medicines Law*, *supra* note 295.

301. *Id.*

302. See 40 *Drug Companies Take Government to High Court over Generic Drugs Plan*, *supra* note 297. See also Claire Keeton, *S. African Government and Drug Giants in Court over Medicine Prices*, AGENCE FRANCE PRESSE, Mar. 4, 2001. The production of generic medicines locally or through parallel imports of drugs will lead to cheaper prices. *Id.* Brazil and India have both offered resources to help manufacture cheaper generic drugs, Brazil through technology transfer and India by supplying raw materials. *Id.*

303. See Press Release, Médecins Sans Frontières, *Pharmaceutical Industry Must Stop Obstructing Access to Medicine in South Africa* (Mar. 1, 2001), available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author). Cf. Snyder, *supra* note 227, at 182 (reviewing the fact that South Africa signed the TRIPs Agreement and changed its domestic laws in order to fully comply). See also Médecins Sans Frontières, *Background Information: South Africa Medicines Law*, *supra* note 295 (providing that the TRIPs Agreement states that parallel importation cannot be subject to challenge at the WTO as countries are free to decide for themselves the extent of parallel importation they can allow in their national laws). See generally (Response) *Letter from European Commissioner Pascal Lamy re: South Africa*, (Mar. 2, 2001) (written by Pascal Lamy, European Commissioner), [hereinafter (Response) *Letter from European Commissioner Pascal Lamy*], available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author); *Open Letter to Members of the European Parliament*, *supra* note 296.

304. See TRIPs Agreement, *supra* note 7 and text accompanying *supra* notes 166 & 164, art. 6, 31; Gavin Yamey, *Agencies Urge End to Global Trade Restrictions on Essential Medicines*, BRITISH MEDICAL JOURNAL, Dec. 2, 1999, available at <http://www.accessmed-msf.org> (last visited Feb. 26, 2001) (on file with author); (Response) *Letter from European Commissioner Pascal Lamy*, *supra* note 303. See also Snyder, *supra* note 227, at 197 (clarifying that the laws do not abrogate patent rights but in fact simply provides the Health Minister with the power to authorize parallel imports in accord with TRIPs); Médecins Sans Frontières, *PETITION: Drop the Case! Support the Struggle for Medicines in South Africa*, (Mar. 2001) [hereinafter *PETITION: Drop the Case*] (noting that the legislation is

The legislation came under sharp criticism from the United States, its drug industry and the European Community.³⁰⁵ Both the United States government and the European Union supported the pharmaceutical companies' argument that the Act was a violation of the TRIPs agreement and placed pressure on South Africa to drop the Act.³⁰⁶ On February 18, 1998, a suit was brought against the Government of South Africa, by forty-two³⁰⁷ pharmaceutical manufacturers alleging that the Act was un-

consistent with South Africa's obligations as a member of the WTO), available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author).

305. See Long & D'Amato, *Introduction: A Trip Begins*, *supra* note 14, at 7 (noting that South Africa's attempt to "circumvent" its patent regime has led to heated debates over the role of patent protection in the medical community); Snyder, *supra* note 227, at 177 (explaining that the International Federation of Pharmaceutical Manufacturers stated they would retaliate against South Africa by withholding new drugs unless South Africa changed the legislation). See Boseley, *supra* note 147; Donald G. McNeil Jr., *As Devastating Epidemics Increase, Nations Take on Drug Companies*, N.Y. TIMES, Jul. 9, 2000, available at <http://www.accessmed-msf.org> (last visited Feb. 26, 2001) (on file with author); Vulliamy, *supra* note 296; *Open Letter to Commissioner Pascal Lamv*, *supra* note 296; *Trade: U.S. to Consider Poor Countries' Need for Drugs. Health Care: Call for End to Trade Pressures in Health-Related Disputes*, THE FINANCIAL TIMES, Dec. 3, 1999, available at <http://www.accessmed-msf.org> (last visited Feb. 26, 2001) (on file with author).

306. See Médecins Sans Frontières, *Background Information: South Africa Medicines Law*, *supra* note 295. See also Snyder, *supra* note 227, at 177 (reporting that in reaction to the new law USTR Charlene Barshefsky placed South Africa on the Watch List for countries which fail to adequately protect intellectual property).

307. Three companies withdrew from the suit leaving only 39 pharmaceutical companies. See *Open Letter to 39 Pharmaceutical Companies*, *supra* note 296. The 39 companies who brought suit are:

The Pharmaceutical Manufacturers' Association of South Africa; Alcon Laboratories (S.A.) (Proprietary) Limited; Bayer (Proprietary) Limited; Bristol-Myers Squibb (Proprietary) Limited; Byk Madaus (Proprietary) Limited; Eli Lilly (South Africa) (Proprietary) Limited; Glaxo Wellcome (South Africa) (Proprietary) Limited; Hoechst Marion Roussel Limited; Ingelheim Pharmaceuticals (Proprietary) Limited; Janssen-Cilag Pharmaceutical (Proprietary) Limited; Knoll Pharmaceuticals South Africa (Proprietary) Limited; Lundbeck South Africa (Proprietary) Limited; Merck (Proprietary) Limited; MSD (Proprietary) Limited; Novartis South Africa (Proprietary) Limited; Novo Nordisk (Proprietary) Limited; Pharmacia & Upjohn (Proprietary) Limited; Rhone-Poulenc Rorer South Africa (Proprietary) Limited; Roche Products (Proprietary) Limited; Schering (Proprietary) Limited; Schering-Plough (Proprietary) Limited; S.A. Scientific Pharmaceuticals (Proprietary) Limited; SmithKline Beecham Pharmaceuticals (Proprietary) Limited; Universal Pharmaceuticals (Proprietary) Limited; Wyeth (Proprietary) Limited; Xixia Pharmaceuticals (Proprietary) Limited; Zeneca South Africa (Proprietary) Limited; Bayer AG; Boehringer-Ingelheim International GmbH; Boehringer-Ingelheim KG; Bristol-Myers Squibb Company; Byk Gulden Lomberg Chemische Fabrik GmbH; Dr. Karl Thomae GmbH; Eli Lilly and Company; F. Hoffman-La Roche AG; Merck KGaA; Merck & Co., Inc.; Rhone-Poulenc Rorer S.A.; SmithKline Beechman.

Id. See Press Release, Médecins Sans Frontières, NGOs Denounce the Lack of Transparency in Multi-national UNAIDS ARV Drug Deal for Kenya: NGOS act to Treat Pa-

constitutional.³⁰⁸ Harvey Bale, the director general of the International Federation of Pharmaceutical Manufacturers stated the industry must pursue the suit because the industry must protect pharmaceutical patents as "the foundation of research and development."³⁰⁹ Additionally, the pharmaceutical industry asserts that treating AIDS or other diseases that are prevalent in developing countries cannot be solved by attacking pharmaceutical prices.³¹⁰ Rather the industry asserts that ensuring access to medicines involves issues other than price such as health care infrastructure, providing proper care and treatment, lack of computers and instituting distribution systems.³¹¹ The lawsuit imposed an injunction on the implementation of the Act.³¹² In the three years since the legislation was under injunction, over 400, 000 South Africans have died of AIDS, most

tients and Call on Big Pharmaceutical Companies to Lower Prices as Promised (Feb. 21, 2001), available at <http://www.accessmed-msf.org/msf/accessmed/reports/2001/02/> (last visited Feb. 26, 2001) (on file with author); Press Release, Médecins Sans Frontières, Pharmaceutical Industry Must Stop Obstructing Access to Medicine in South Africa, *supra* note 303.

308. See Rosenberg, *supra* note 219; Vulliamy, *supra* note 296; *Indian Firm Offers AIDS Cocktail for \$1 a Day*, REUTERS, Feb. 9, 2001, available at <http://www.accessmed-msf.org> (last visited Feb. 26, 2001) (on file with author); *Open Letter to Commissioner Pascal Lamy*, *supra* note 296; Press Release, Médecins Sans Frontières, Drop the Case!, *supra* note 296. See also Sarah Boseley, *Struggle for Cheap Medicines: AIDS Drugs War Between the Big Firms and the Poor Countries*, THE GUARDIAN, Nov. 27, 1999 (noting that when the South African government tried to produce AIDS medications cheaply and allow parallel imports from countries which produce them cheaply, they were met with a lawsuit), available at <http://www.accessmed-msf.org> (last visited Feb. 26, 2001) (on file with author); Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6 (asserting that the industry felt the law was unconstitutional because it gave the South African health minister power to neglect the country's patent laws).

309. Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6.

310. *Id.* See Keeton, *supra* note 302.

311. See Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6.

312. See *id.* See Donald G. McNeil Jr., *South Africa's Bitter Pill for World's Drug Makers*, N.Y. TIMES, Mar. 29, 1998 Sec.3, at 1; Sternberg, *supra* note 296; Press Release, Joint MSF/Oxfam, 29 Drug Companies versus South Africa: People Die for Lack of Affordable Drugs as Inhumane Industry Ignores Reality (Mar. 5, 2001), [hereinafter Press Release, Joint MSF/Oxfam, 29 Drug Companies versus South Africa], available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author); Press Release, Médecins Sans Frontières, Voices Around the World Condemn Drug Industry Hypocrisy: New Evidence Shows Why Industry Legal Arguments Don't Stack Up (Apr. 17, 2001) [hereinafter Press Release, Voices Around the World Condemn Drug Industry Hypocrisy], available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author). See also Press Release, Médecins Sans Frontières, Voices of People Living with HIV to be Heard by South African Court: MSF Welcomes Judge's Decision to Accept Amicus Brief (Mar. 6, 2001) [hereinafter Press Release, Voices of People Living with HIV to be Heard by South African Court] (noting that the legislation has now been blocked from coming into force for three years), available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author).

of whom were unable to acquire affordable treatments.³¹³ During that time major pharmaceutical companies closed their South African factories.³¹⁴ South African Health Minister, Dr. Nkosasana Zuma stated that the change in law was a fight for people who need medicine.³¹⁵ Dr. Zuma asserted that governments must be able to buy medicines cheaply in order to distribute them to the poor.³¹⁶ For South Africa the fight with the multi-nationals is a consequence of the real fight to save the lives of millions who are dying of AIDS.³¹⁷

While the pharmaceutical industry has been trying to improve its image, so as to be viewed as helping fight the AIDS crisis, they staunchly resist diminished patent protection.³¹⁸ For the industry, suing a poor nation, that is trying to acquire copied generic drugs due to their inability to afford brand name drugs, is legitimized by the belief that the industry must protect patents.³¹⁹ The industry is particularly concerned that if the South African legislation stands, other poor countries will embody similar legislation.³²⁰ Additionally, the industry is concerned that if developing nations are permitted to buy cheaper generic drugs, American consumers will demand the same.³²¹ When the lawsuit was filed it had the support of the United States government, which had once again named South Africa to the Special 301 Watch List, and continued to pressure South Africa to prevent the use of compulsory licensing and parallel imports.³²² Additionally, European Commissioner, Pascal Lamy, stated that the Community supported intellectual property protection through a full implementation of the TRIPs Agreement to be essential for investment in R&D for medicines to protect against serious diseases.³²³ Thus the

313. Press Release, Médecins Sans Frontières, Drop the Case!, *supra* note 296.

314. See McNeil Jr., *supra* note 312, at 1. Bristol-Myers Squibb, Pharmacia & Upjohn and Eli Lilly shut down in South Africa after the legislation was imposed. *Id.*

315. See *id.* The South African law now provides that pharmacists must tell their customers when a cheaper generic products exists and must sell that medicine to the patient if desired. *Id.*

316. See *id.*; Sternberg, *supra* note 296. Cf. Snyder, *supra* note 227, at 185 (noting that Dr. Zuma has also stated that the law's intent is not to provide her with a power to eliminate all pharmaceutical patent rights).

317. See McNeil Jr., *supra* note 312, at 1.

318. See Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6.

319. *Id.*

320. *Id.*

321. See *id.* (noting that pharmaceutical companies derive an annual profit of \$126 billion from the United States market).

322. See *id.*; McNeil Jr., *supra* note 305; McNeil Jr., *supra* note 312, at 1; Vulliamy, *supra* note 296; Yamey, *supra* note 304; Open Letter to Commissioner Pascal Lamy, *supra* note 296.

323. (Response) Letter from European Commissioner Pascal Lamy, *supra* note 303. This letter presented a response to the request of Médecins Sans Frontières to show full

Commissioner chose not to withdraw the statement of previous Commissioner Sir Leon Brittan condemning the legislation.³²⁴

Activists in the United States brought public attention to the continued pressure of the United States on South Africa to modify the Medicines Act.³²⁵ While the United States Trade Representative's office has long been a supporter of the industry's position on non-patented drugs, in the face of the growing controversy about the spread of disease in developing countries and the extreme price of drugs, they can no longer stand firmly behind the industry.³²⁶ In September, 1999 the United States dropped the threat of sanctions on South Africa in light of its attempt to deal with the AIDS Epidemic.³²⁷ Both the United States and the European Union softened their position in light of the public protest.³²⁸ Notably, in early May of 2000, USTR Charelene Barshefsky supported the signing of an

support for actions to promote access to medicines. *Id.* The Commissioner declined to withdraw a previous letter of the Commission that had criticized the enactment of South Africa's Act. *Id.* In the same breath though, the Commissioner stated that the Community would not take a position in matters that were within the internal constitutional affairs of South Africa. *Id.*

324. See Boseley, *supra* note 308 (noting that in March 1998, Sir Leon Brittan former European commissioner warned that legislation allowing parallel imports negatively affects the European pharmaceutical industry); see also (Response) *Letter from European Commissioner Pascal Lamy, supra* note 303. But see *Letter from MSF to Commissioner Pascal Lamy, supra* note 295 (noting that the Commission had previously taken a stand on behalf of the pharmaceutical companies at the onset of the court case).

325. See Boseley, *supra* note 308; Vivian Hoffmann, *Health Groups Say Poor Nations Need Access to Generic Drugs*, BOSTON GLOBE, Nov. 27, 1999, available at <http://www.accessmed-msf.org> (last visited Feb. 26, 2001) (on file with author). See also *40 Drug Companies Take Government to High Court over Generic Drugs Plan, supra* note 297. ACT UP activists demanded that the Pharmaceutical Companies drop the lawsuit, stop blocking access to cheaper generic drugs, allow for compulsory licenses, and discontinue patent extensions. *Id.* Additionally, ACT UP demanded the Bush Administration, condemn the lawsuit, drop the WTO dispute with Brazil, and clarify that the U.S. government's policy towards impoverished countries is not limited to sub-Saharan African countries, and AIDS antiretroviral medication. *Id.*

326. See Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6. This is an extremely unusual stance from the government who has long received financial support from the drug industry in election campaigns. *Id.* In the most recent election the industry spent \$80 million to help elect President Bush and the Republicans. *Id.*

327. See Rosenberg, *supra* note 219; *Trade: U.S. to Consider Poor Countries' Need For drugs. Health Care: Call for End to Trade Pressures in Health-Related Disputes, supra* note 305. See also Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6 (explaining that the Clinton administration decision to stop pressing South Africa to change the legislation is also supported by the Bush administration); Vulliamy, *supra* note 296; (noting that Al Gore about turned and stated that he was not afraid to stand up to the pharmaceutical industry).

328. Médecins Sans Frontières, *Background Information: South Africa Medicines Law, supra* note 295.

Executive Order to combat the spread of HIV/AIDS in Africa.³²⁹ The Executive Order, while a positive step, was restricted to sub-Saharan Africa, ignoring the plight of the poor in other developing countries.³³⁰

In late February of 2001, the Bush administration through the USTR issued a statement that indicated it will make the need to protect America's investment in intellectual property consistent with the need to work with countries to develop programs to treat the AIDS crisis.³³¹ However the loss of support from the government did not deter the pharmaceutical companies.³³² Despite the consistent opposition to pharmaceutical patents by international aid agencies such as Oxfam and Médecins Sans Frontières, stating that access to affordable medicines would save lives if the legislation was permitted, the pharmaceutical corporations continued to attack South Africa over the law.³³³ The health needs of poor countries must be a priority even if it means violating drug patents.³³⁴

The lawsuit began at the High Court in Pretoria, South Africa on March 5, 2001.³³⁵ On the second day of hearings before the South Afri-

329. See Press Release, Office of the United States Trade Representative, USTR Barshfsky Welcomes HIV/AIDS Executive Order, (May 10, 2000) (noting that the order provides a proper balance between the need to ensure that intellectual property rights are protected and the needs of African countries are protected in the face of the AIDS crisis), available at www.ustr.gov (on file with author). See also Sternberg, *supra* note 296. President Clinton issued the order to make inexpensive drugs and medical technologies available to AIDS ravaged Africa. *Id.* The order provides that the U.S. government will not impose restrictive intellectual property rights on pharmaceuticals needed to provide access to HIV drugs. *Id.*

330. See Thalif Deen, *Health: Cheaper Aids Drugs a Myth, Says Medical Aid Agency*, INTER PRESS SERVICE, May 11, 2000. In December of 1999 President Clinton pledged that the United States would "henceforth implement its health care and trade policies in a manner that ensures that people in the poorest countries won't have to go without medicine they so desperately need." *Id.*

331. See Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6. See also *HIV/AIDS: Bush to Keep Intellectual Property Policy*, AMERICAN HEALTH LINK, Feb. 22, 2001 (indicating that the Bush administration will uphold the executive order issued by the Clinton administration the previous year).

332. Sternberg, *supra* note 296. Alan Holmer, President of PhrMA, criticized the executive order as discriminating against intellectual property laws. *Id.* PhrMA asserts that while AIDs is a problem weakening intellectual property is not the solution. *Id.*

333. See Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6; Keeton, *supra* note 302; Press Release, Joint MSF/Oxfam, 29 Drug Companies versus South Africa, *supra* note 312. See also *Companies Agree to Cut Prices of HIV Drugs in Poor Nations*, *supra* note 299 (noting that the Pharmaceutical Research and Manufacturers of America denounced the Executive Order as setting an undesirable and inappropriate precedent allowing for exceptions to pharmaceutical patents).

334. See Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6.

335. *Open Letter to Commissioner Pascal Lamy*, *supra* note 296.

can High Court, Judge President Bernard decided to permit an *amicus curiae* brief submitted by a South African NGO, Treatment Action Campaign (TAC), which represents people living with HIV.³³⁶ TAC representative Axckie Achmat stated that "The exorbitant prices of medicines in South Africa cannot be justified by the need to finance R&D, given that Africa comprises only 1% of global pharmaceutical sales."³³⁷ Allowing the TAC application indicated that the Judge President believed that people infected with AIDS had a compelling interest in the case and in the matter of access to affordable medicines.³³⁸ The pharmaceutical industry had tried to prevent the amicus brief from being admitted into evidence as the brief gives evidence that for the vast majority of people with HIV in South Africa, brand name medicines are unaffordable.³³⁹ Additionally, it placed the onus on the pharmaceutical industry to justify why their pharmaceuticals are so expensive and their patents are protected so vigorously, when affordable drugs can be produced generically for the millions of people who are infected with the disease.³⁴⁰ In order to permit the industry complainants time to reply to the brief, and justify their high prices, the case was scheduled to resume beginning April 18, 2001.³⁴¹

Worldwide support poured in against the pharmaceutical industry suit.³⁴² MSF began a worldwide petition calling on the companies to

336. Briefing Paper: The Ins and Outs of the PMA Affidavits: A Summary and Response to the Affidavits submitted by the Pharmaceutical Manufacturers' Association in South Africa (April 2001) [hereinafter Briefing Paper: The Ins and Outs of the PMA Affidavits], at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author); Press Release, Voices of People Living with HIV to be Heard by South African Court, *supra* note 312.

337. Briefing Paper: The Ins and Outs of the PMA Affidavits, *supra* note 336. See also Press Release, Voices Around the World Condemn Drug Industry Hypocrisy, *supra* note 312 (noting also that the investment into R&D is not primarily for diseases that affect developing countries).

338. Briefing Paper: The Ins and Outs of the PMA Affidavits, *supra* note 336.

339. Press Release, Voices of People Living with HIV to be Heard by South African Court, *supra* note 312.

340. *Id.*

341. *Id.* The pharmaceutical company litigants sought an additional four months, however the Judge only granted them three weeks to present data justifying their high prices. *Id.* See Briefing Paper: The Ins and Outs of the PMA Affidavits, *supra* note 336.

342. Press Release, Voices Around the World Condemn Drug Industry Hypocrisy, *supra* note 312. See *PETITION: Drop the Case*, *supra* note 304; Médecins Sans Frontières, "Drop the Case" Global Petition Results: Public Support for South Africa (Apr. 18, 2001), available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author). Political Messages calling for the pharmaceutical companies to withdraw from the suit came from various countries. *Id.* Included amongst the political voices calling for withdrawal from the suit were: The European Parliament in an emergency resolution passed on March 15, 2001 entitled, Access to Medicines for AIDS Patients in the Third World; Nelson Mandela former President of South Africa; Minister of Development, Germany; Prime

drop the lawsuit.³⁴³ Over 250,000 people from over 130 countries signed the petition reflecting the worldwide anger at the hypocrisy of the pharmaceutical industry.³⁴⁴ On April 19, 2001, in response to the resounding global denouncement of their lawsuit, the drug companies unconditionally dropped the suit.³⁴⁵ With their withdrawal from the suit, the 1997 Medicines Act took force allowing parallel importation of affordable medicines and legitimizing the use of quality generic drugs.³⁴⁶ This victory for South Africa also creates a resounding precedent for all developing countries who need better access to health care.³⁴⁷ The message that the case sends is that "lives should and can take precedence over patents," providing a change in the traditional power held by drug companies over developing countries.³⁴⁸ The change that took place in the United States government during the buildup to the lawsuit in South Africa must be followed through for all developing countries. Just as public health and the growing AIDS crisis in South Africa began to influence discussions on the protection of intellectual property, the USTR must follow and support all developing nations' quest for affordable medicines. The United States must not only be held accountable to this statement, it must also apply such leniency to all pharmaceutical patents for diseases prevalent in developing countries, such as tuberculosis, malaria, and sleeping sickness.

The Industrialized Nations and their pharmaceutical industries must not ignore the needs of developing countries that suffer from infectious diseases. Africa may have the highest proportion of people infected with

Minister of Denmark; Minister of Foreign Affairs, Denmark; Prime Minister of the Netherlands; Minister of Development Aid, the Netherlands; La Ministre Federale de la Santé Publique, Belgium; Le Secrétaire d'Etat à la Coopération au Développement, Belgium. *Id.* Additionally, Gro Harlem Brundtland, Director General of the World Health Organization sent a political message supporting the South African government's effort to improve access to essential medicines. *Id.* Support came from over 132 countries and 131 non-governmental organizations. *Id.*

343. *PETITION: Drop the Case*, *supra* note 304 (calling on the 39 pharmaceutical companies to withdraw from the case blocking the implementation of the legislative Act). See Press Release, Voices Around the World Condemn Drug Industry Hypocrisy, *supra* note 312.

344. Press Release, Voices Around the World Condemn Drug Industry Hypocrisy, *supra* note 312 (noting that the industry claims to be fighting AIDS yet sought to undermine South Africa's efforts to provide affordable medicines).

345. Press Release, Joint MSF-Oxfam-TAC, Drug Companies in South Africa Capitulate Under Barrage of Public Pressure: Powerful Precedent Set for Other Developing Countries (Apr. 19, 2001), available at <http://www.accessmed-msf.org> (last visited May 21, 2001) (on file with author).

346. *Id.*

347. See *id.*

348. *Id.*

AIDS, but the disease is equally as harmful to people in many other developing countries.³⁴⁹ India has reported at least four million infected people, but that number may be up to five times higher when considering non-reported cases.³⁵⁰ After sub-Saharan Africa, the Caribbean has the highest rate of HIV infection.³⁵¹ While AIDS is considered a manageable disease in the industrialized world, the cost of AIDS drugs in the developing world gives the 32.5 million people infected with the disease in poor countries less chance of survival.³⁵² This should not be the case for anyone in the world today. Drug therapies exist to battle the spread of the disease.

Brazil is one country that has put the needs of its AIDS infected people above the patents required by the pharmaceutical industry.³⁵³ Through Brazil's use of compulsory licenses, the government makes generic copies of brand name drugs, reducing the cost of medicines by 79%.³⁵⁴ There is no need to keep the necessary medicines out of the reach of the poor nations, and allowing the manufacture of cheaper medicines should not be barred simply because wealthy nations insist on intellectual property protection. Countries should be encouraged to follow Brazil's model and should welcome Brazil's offer to transfer its technology to other developing countries.³⁵⁵

The offers of the pharmaceutical industry to lower drug prices are limited and do not do enough to ensure AIDS drugs are affordable.³⁵⁶ Developing countries must reject patents on pharmaceutical products in order to save their people from infectious diseases.³⁵⁷ While AIDS has received the most press coverage, developing countries are affected by numerous infectious diseases that must be countered.³⁵⁸ Cost should not be a factor in determining whether a person lives or dies. Fear of sanctions on trade from industrialized countries must not be allowed to pre-

349. See Rosenberg, *supra* note 219.

350. *Id.*

351. *Id.* In the Caribbean, more than one in 50 adults are infected and the disease is spread primarily through heterosexual contact. *Id.*

352. *Id.*

353. See *id.* Brazil introduced triple therapy cocktails of antiretrovirals, used in many industrialized countries, in order to prevent the climbing AIDS death rate. *Id.*

354. *Id.* Notably the AIDS death rate in Brazil has been cut by 50%. *Id.*

355. See *id.* Some assert that Brazil's program may not be easily duplicated by all developing nations, which may not have the advantages of Brazil. *Id.* However millions of people live in countries that can emulate Brazil and create an AIDS infrastructure with the availability of international assistance. *Id.*

356. See *id.*

357. See *id.*

358. See *id.*

vent developing countries from taking action to ensure access to essential medicines.

VI. AN ALTERNATIVE PLAN: APPROACHING THE END OF THE TRANSITION PERIOD

Now is the time to make access to essential medicines affordable. Notably, "[i]n the world's poorest countries, most people, particularly the poor, have to pay for health care from their own pockets at the very time they are sick and most in need of it."³⁵⁹ This is especially relevant in light of the fact that according to the WHO, people in developing countries are now confronting both the imminent threat of infectious diseases and overwhelming epidemics of non-contagious diseases.³⁶⁰ Although the United States is now taking some steps to consider the global AIDS crisis,³⁶¹ these actions are merely small measures in the face of a tremendous problem that encompasses more than just South Africa, and more than just AIDS.

The TRIPs agreement was included in the last round of GATT negotiations, and many developing countries are now bound to it in order to remain members of the WTO. By the year 2006, all developing countries are expected to have implemented the TRIPs Agreement into their own national legislation. Where previously developing countries were able to exclude pharmaceuticals from patent provisions, under the TRIPs WTO countries must impose both process and product patents for all pharmaceuticals.³⁶² This will be a crushing blow to developing countries unless the industrialized countries consider the alternatives that are available. Developed nations must work with developing countries which have difficulty in complying with the provisions of TRIPs.³⁶³ In the dis-

359. WORLD HEALTH ORGANIZATION, *THE WORLD HEALTH REPORT 2000 HEALTH SYSTEMS: IMPROVING PERFORMANCE* xviii (2000) [hereinafter *WORLD HEALTH REPORT 2000*].

360. See Fidler, *supra* note 19, at 191. Non-contagious diseases include heart and lung diseases. *Id.*

361. See Press Release, Office of the United States Trade Representative, USTR Barshfsky Welcomes HIV/AIDS Executive Order, *supra* note 329; Press Release, Office of the United States Trade Representative, The Protection of Intellectual Property and Health Policy, *supra* note 90. See also Cooper, Zimmerman & McGinley, *supra* note 91, at A1, A6.

362. See TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 155, art. 27. Elliott, *supra* note 58, at A11; Rosenberg, *supra* note 219; *Implications of Uruguay Round*, *supra* note 7.

363. See Daniel Pruzin, *WTO Members Approve Work Program For Addressing Implementation Issues*, Bureau of National Affairs, Inc., Washington D.C. (Jun. 23, 2000) (noting that assistance is particularly needed for those countries who have financial difficulties in creating an intellectual property infrastructure), available at <http://>

cussion of implementation of TRIPs there is a need for the inclusion of special and more flexible provisions for developing countries, particularly as it translates into protecting public health.³⁶⁴ The TRIPs agreement must find a better balance between rich and poor countries.³⁶⁵

A. *Amend or Modify the TRIPs Agreement to Provide Implementing Assistance*

Under Article 71 of the Agreement, the TRIPs Council may begin a review in the event of new developments which might justify modifications.³⁶⁶ As the TRIPs Agreement currently is interpreted, the industrialized countries reap the most benefits from patent protection for pharmaceuticals. By amending the agreement, a more equitable result could be achieved. Two areas are in need of immediate change: first the current twenty year patent term should be decreased; and second the transition period must be lengthened for developing countries.

1. Decrease the Current 20 Year Patent Term

Decreasing the current 20 year patent term required for pharmaceuticals patents would eliminate a barrier against developing countries.³⁶⁷ It is solely in the interest of the pharmaceutical corporations ability to make profits that the 20 year patent requirement is imposed on developing

www.wtowatch.org/news/index.cfm?ID=2106 (lasted visited Sept. 30, 2000) (on file with author).

364. See *id.* At a special session of the WTO's General Council on July 3, in Geneva, trade officials from developing countries argued that "the technical, administrative, and financial problems they face in implementing and complying with existing WTO Agreements; should be addressed before members can consider negotiations in new trade round." *Id.* Particularly the developing nations are calling for the implementation of numerous issues raised by a number of developing countries in a draft of WTO's ministerial text. *Id.* Paragraph 21 calls for the immediate addition of special and more flexible provisions for developing countries to WTO agreements in numerous areas, including TRIPs. *Id.* Paragraph 22 calls for a full and comprehensive review of the problems faced by members in implementing existing WTO agreements. *Id.* See *TRIPs Under Scrutiny at WTO*, THE HINDU, Oct. 18, 2000.

365. See *TRIPs Under Scrutiny at WTO*, *supra* note 364. See also Rowe, *supra* note 254, at 142 ("[t]he voices of developing nations should not be muted by the chatter of the TRIPs Agreement").

366. See McCabe, *supra* note 9, at 63.

367. See Raghav Narsalay, *India: Evolving a WTO Regime- India's Agenda*, BUSINESS LINE, Aug. 10, 2000, available at 2000 WL 24947965; Patents: *Private Rights and Public Interests*, *supra* note 124. Cf. Weissman, *supra* note 10, at 1073 (introducing the fact that there is no inherent reason to prevent shortening the period of patent protection).

countries.³⁶⁸ Such a requirement prevents generic drugs, which could be produced and sold at a fraction of the price, from being made available to the poor and needy in developing countries.³⁶⁹ The current 20 year term imposes a significant restriction on developing countries and must be lifted to provide some leniency to developing countries.

2. Increase the Transition Period

Countries should advocate for increasing the transition period established for implementing the TRIPs requirements.³⁷⁰ While developed countries were required to meet the obligations of TRIPs by 1996, developing countries, which have not previously provided protection to pharmaceuticals, were given until January 2005 to implement the measurements.³⁷¹ They need more time to comply with the rules on intellectual property and advocate change and more compassion on the need to ease drug patents for poorer countries.³⁷² Developing countries are skeptical whether the benefits of the Uruguay round are reaching them. While some developing countries have scrambled to make their patent laws TRIPs compliant, in order to prevent potential sanctions on their trade exports, this has proved to be to the detriment of the poor who will be unable to afford essential drugs.³⁷³

B. Health and Essential Medicines Should Be Basic Human Rights

Many human rights activists assert that the TRIPs provisions on the patenting of pharmaceuticals violates basic human rights by compromis-

368. See Madeleine Bunting, *The Profits that Kill: Dying for Drugs: Intellectual Property Agreements Are Making Too Much Money for the West*, THE GUARDIAN, Feb. 12, 2001, p. 19.

369. See *id.*

370. See Narsalay, *supra* note 367.

371. TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 32, art. 65, 66. See Mike Moore, WTO Director General, *Yes, Drugs for the Poor—and Patents as Well*, *supra* note 223; *Implications of Uruguay Round*, *supra* note 7; Kamal, *supra* note 32.

372. See *Optimism About Malaria Vaccine Grows*, *supra* note 267.

373. See Judith Achieng', *Health Trade-Kenya: New Patenting Law May Be Harmful to Health*, INTER PRESS SERVICE, Nov. 18, 1999. Kenya, for example, introduced a bill bringing its legislation in line with the TRIPs requirements, but such legislation failed to provide safeguards for national health emergencies. *Id.* By imposing TRIPs compliant legislation multinational pharmaceutical companies will attain a monopoly on pharmaceutical prices thus driving the cost of drugs out of the reach of the poor. *Id.* MSF has urged Kenya to legislate compulsory licensing and parallel imports for medicines before enacting TRIPs compliant legislation. *Id.* See also *Kenya Seeks Legal Path to Cheaper AIDS Drugs*, AGENCE FRANCE PRESSE, Mar. 6, 2001 (noting that Kenya has now introduced plans to relax its stringent patent laws by introducing a bill to legalize parallel imports).

ing the ability of poor countries to access essential medicines.³⁷⁴ Notably, in August of 2000, the WTO was indicted by a United Nations panel for failing to respect human rights in the implementation of TRIPs.³⁷⁵ This failure to respect human rights has resulted in making necessary medicines for deadly diseases unaffordable to poor nations.³⁷⁶

When developing countries agreed to sign on to the TRIPs, despite many objections, they did so because of various provisions that were meant to reflect the needs of their countries.³⁷⁷ Article 8 of the TRIPs, which promises to protect public health, is one such provision.³⁷⁸ Article 8 should be utilized to demand that as there is an essential right to health, and thus essential medicines should be made available, regardless of patent laws.³⁷⁹ Additionally, Article 27 of the Agreement contains a public health exception to the patent requirement which includes the protection of human life or health.³⁸⁰ This public health exception should allow countries with legitimate health concerns to deny a patent on a particular drug or all drugs.³⁸¹ Taken together Article 8 and Article 27 must be used to protect the health needs of developing countries. This view was reinforced by the WHO in its Revised Drug Strategy, which urged Mem-

374. See Fidler, *supra* note 19, at 214; D. Ravi Kanth, *WTO Allowed Drugs to be Priced Beyond Reach of the Poor: UN Panel*, BUSINESS TIMES, Aug. 22, 2000, available at 2000 WL 25565053.

375. See Kanth, *supra* note 374. The UN Commission on Human Rights created a Sub-Commission on the Promotion and Protection of Human Rights. *Id.*

376. See *id.* The pharmaceutical companies continue to assert that because they spend millions conducting R&D, they have the right to charge prices they deem as suitable. *Id.*

377. See *Implications of Uruguay Round*, *supra* note 7. The TRIPs Agreement provides an exception to product and process patents for inventions that may be contrary to public order or morality, allowing developing countries an exclusion from patentability. See TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 155, art 27 (2). See also TRIPs Agreement, *supra* note 7 and text accompanying *supra* notes 164 & 166 (detailing the provisions surrounding compulsory licenses and parallel imports).

378. TRIPs Agreement, *supra* note 7, art. 8. "Members may . . . adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development . . ." *Id.*

379. See *id.*

380. TRIPs Agreement, *supra* note 7 and text accompanying *supra* note 155, art. 27(2). See Weissman, *supra* note 10, at 1099.

381. See Weissman, *supra* note 10, at 1099-1100. The way the Article is written requires that the patent exception be linked to a prohibition against commercial exploitation of the invention. See *id.* at 1100. This linkage limits the scope of the exception, particularly as it applies to generic companies. *Id.* However it does provide an alternative to developing countries. *Id.* Additionally, the requirement of what constitutes "necessary" would present a hurdle that developed countries would likely attempt to use against the developing countries. See *id.* at 1101, 1106. It is likely that a developing country attempting to invoke the exception would have to argue that there are no means less inconsistent with the Agreement to achieve the goal of providing access to essential medicines. *Id.* at 1106.

ber States to ensure equitable access to essential drugs.³⁸² The TRIPs Agreement should not act as an impediment to the public health of people in developing countries. Rather, to be consistent with Article 8 of TRIPs and the goals of WHO as specified in the Strategy, the priority must be placed in the health and well being of all the world's people.

1. Parallel Imports and Compulsory Licenses

Making essential health needs a basic human right can be done in a manner consistent with the TRIPs. In developing countries where a majority of people live below the poverty line, it is inexcusable to demand that those people pay the exorbitant costs associated with patented drugs.³⁸³ When the choice is between making profits or saving lives, the choice should be simple. If the goal is truly to help developing nations develop, patent laws that inhibit the health of nations should not be a priority when there is a cheaper alternative available.³⁸⁴ Exceptions to patent protection on pharmaceuticals for essential medicines, can be considered consistent with TRIPs provisions on parallel imports and compulsory licenses. The WTO must clarify the rules as provided for in TRIPs to give developing countries the undeniable right to compulsory licenses and parallel imports for essential pharmaceuticals.³⁸⁵

a. Parallel Imports

Once a country has sold a product to another country, it has received the benefit of its patent and its rights to that product are thus exhausted. If the country that bought the product then chooses to sell the product at a lower price no harm has been done to the patent holder.

During the Uruguay Round the issue of exhaustion of patent rights was not addressed in the text of the Agreement.³⁸⁶ Recently this has been clarified by the WTO. According to WTO General Director Mike Moore, if a government authorizes parallel imports of a drug from coun-

382. See WHA 52.19, *Revised Drug Strategy*, *supra* note 30. The strategy stated specifically that Member States should "explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs." *Id.*

383. See *id.* (urging Member States to safeguard access to essential drugs).

384. See Elliott, *supra* note 58, at A11. No one should die because they could not afford the medications to treat their illnesses. See *id.* Developing countries should be allowed to make cheap copies of western drugs, such as in the case of India, who makes 70% of its own drugs. *Id.* Those poorer developing countries who cannot afford to manufacture their own drugs should be allowed to benefit by importing the cheaper generic versions in order to ensure access to essential medicines. See *id.*

385. See *id.*

386. See *Implications of Uruguay Round*, *supra* note 7.

tries where the drug is available at a cheaper price, that authorization cannot be challenged at the WTO.³⁸⁷ The South African example illustrates that the use of parallel imports does not violate international law but allows a country to act in a manner consistent with their TRIPs obligations.³⁸⁸

b. Compulsory Licenses

Compulsory licenses allow a local pharmaceutical company to manufacture generic copies of patented pharmaceuticals at lower prices by forcing multinational corporations to issue a license in exchange for a reasonable royalty.³⁸⁹ Compulsory licenses should be permitted for public interest in order to prevent the establishment of barriers to the attainment of basic health care needs.³⁹⁰

While compulsory licensing might appear an easy solution, industrialized countries and their pharmaceutical industries are hesitant to allow them for pharmaceutical products.³⁹¹ Developing countries that have at-

387. Mike Moore, WTO Director General, *Yes, Drugs for the Poor—and Patents as Well*, *supra* note 223.

388. *Cf.* Snyder, *supra* note 227, at 198 (explaining that South Africa's legislation permitting parallel imports is TRIPs compliant).

389. *See* Rosenberg, *supra* note 219. *See also* Achieng', *supra* note 373; *Patents: Private Rights and Public Interests*, *supra* note 124 (noting that the royalty is fixed according to an inventor's contribution).

390. *See Patents: Private Rights and Public Interests*, *supra* note 124. *See also* Wechkin, *supra* note 38, at 240 (providing that compulsory licenses for pharmaceutical inventions were once viewed as legitimate, in light of the fact that the cost of developing pharmaceuticals in developing countries was often prohibitive and the license provided a means by which the technological pharmaceutical industry could be developed without the ordinary expense); *Implications of Uruguay Round*, *supra* note 7 (arguing the compulsory licensing provisions of TRIPs are excessively restrictive, by not allowing a country to discriminate as to whether a product is imported or locally produced and that the failure to meet the needs of a market should provide a basis for extending a compulsory license).

391. *See* Rosenberg, *supra* note 219. "Of all the tools available to poor countries, compulsory licensing is what the drug companies fear the most, since it represents the most direct assault on control of their patents." *Id.* Notably the United States issues compulsory licenses for items that it feels are important, though generally less life threatening than disease. *Id.* The U.S. has issued compulsory licenses in many anti-trust cases, for tow trucks, stainless steel wheels and corn seeds. *Id.* *See also* Fisch, *supra* note 68, at 300-01 & n35. In the United States compulsory licenses are rarely found. *Id.* There are a few exceptions that exist such as in accordance with the Atomic Energy Act 42 U.S.C. § 2183(g) (1994), the Plant Variety Protection Act 7 U.S.C. § 231 (1994) and the Clean Air Act 28 U.S.C. §§ 1857(h)(6), 7608 (1994). *Id.* Thus if the compulsory licensing of pharmaceuticals was allowed it would add to one of the limited exceptions to United States patent law. *See id.* *Cf.* McCabe, *supra* note 9, at 61 (asserting that developed countries will likely reject compulsory licensing as a valid option, as one of their goals in the negotiation of TRIPs was to restrict the application of compulsory licenses).

tempted to institute compulsory licenses, in accordance with the national emergency exception in Article 31 of TRIPs, are faced with pressure from the pharmaceutical industry and developing countries.³⁹² This pressure must stop. This alternative should be utilized without fear of reprisals.³⁹³ The need for access to infectious disease therapies in the developing world should take priority over the industrialized world pharmaceutical industry's desire to protect their patents. The health crises in developing countries constitute national emergencies. If a country chooses to infringe on a patent by issuing a compulsory license in order to cope with a national emergency, the burden of proof should be on the patent holder to prove that there is no emergency.³⁹⁴ At a minimum, industrialized companies must take steps to ensure that developing countries are not forced to ignore the health needs of its people because of threat of sanctions against countries that use compulsory licensing or parallel imports.³⁹⁵

The TRIPs allows countries facing health emergencies to void patents through compulsory licenses and create their own generic versions, pharmaceutical companies must not be allowed to dictate whether a developing country chooses to utilize that option.³⁹⁶

C. *Help Developing Countries Develop: Allow Work Requirements on Pharmaceutical Patents*

Prior to the TRIPs Agreement many developing countries imposed a work requirement that required an invention to be manufactured domestically to receive patent protection.³⁹⁷ For a patented invention that was manufactured outside of the developing country to receive patent protection within the country, a petition would have to be filed, requesting a license from the government to manufacture the invention domestically.³⁹⁸ Article 27(1) of the TRIPs Agreement provides that patents should be enjoyable whether the products are locally produced or imported.³⁹⁹ This provision has banned work requirements. In developing

392. Rosenberg, *supra* note 219.

393. See Fidler, *supra* note 19, at 210.

394. See Elliott, *supra* note 58, at A11.

395. See Rosenberg, *supra* note 219.

396. See Donald G. McNeil Jr., *Patent Holders Fight Proposal on Generic AIDS Drugs for Poor*, N.Y. TIMES, May 18, 2000, at A5.

397. See McCabe, *supra* note 9, at 61. See also Weissman, *supra* note 10, at 1074 (imposing a requirement that a patent holder "work the patent" in the country where the patent is held).

398. See McCabe, *supra* note 9, at 62. See, e.g., Gutterman, *supra* note 42, at 114-15 (showing that Argentina had a requirement that required local production or processing to occur within two years of issuance of the patent or it would lapse).

399. TRIPs Agreement, *supra* note 7, art. 27. See McCabe, *supra* note 9, at 62.

countries with large poverty-stricken populations, requiring domestic manufacture is not unreasonable. While developed countries might protest against modifying Article 27,⁴⁰⁰ the need for developing countries to facilitate their own economic growth and investment requires that domestic work requirements be reinstated and the restrictive language of Article 27 be deleted. This requirement need not be seen as a preventing foreign corporations from obtaining patents, rather it should be viewed as providing the brand name pharmaceutical companies the opportunity to invest in developing countries by opening manufacturing facilities in those countries.

D. *Elimination of Unilateral Sanctions by the United States*

The DSB of the WTO/GATT may not be the ideal system for enforcement of intellectual property laws, but at least it is facially neutral. The United States should not be allowed to act as the police officer for intellectual property through the use of its Special 301 laws.⁴⁰¹ While the United States claims that they amended Special 301 to ensure that the measure would not conflict with TRIPs and the DSB, the unilateral nature of 301 appears to be in bad faith with the WTO. Numerous countries have been placed on the USTR's Special 301 Watch list for not issuing pharmaceutical patents.⁴⁰² Countries are afraid of retaliation by not issuing patents as such actions discourage investment and thus act as a sanction.⁴⁰³ The United States attempts to foster more protection for intellectual property protection than even TRIPs requires.⁴⁰⁴ The United States TRIPs plus approach has no justification for enforcement in international law.⁴⁰⁵ Governments must be encouraged to resist unilateral pressure. Developing nations cannot be expected to trust a system that is policed solely by the United States.

E. *Price Controls*

Another alternative is found through a system of differential pricing, where pharmaceutical companies charge developing countries less than advanced industrialized countries to ensure that patented technologies

400. See McCabe, *supra* note 9, at 62.

401. See Rowe, *supra* note 254, at 115 (warning that the United States' use of Special 301 undermines the provisions of the WTO).

402. Rosenberg, *supra* note 219.

403. *Id.*

404. See Vicente, *supra* note 6, at 1112 (arguing that the United States requires intellectual property protection "greater-than-TRIPs" requires). But see McCabe, *supra* note 9, at 62 (explaining that TRIPs only established minimum standards and countries could implement more extensive requirements).

405. Médecins Sans Frontières, *Report to Thailand*, *supra* note 22.

are not priced at unreasonable levels.⁴⁰⁶ New Zealand provides an example of a country that has tried to comply with the GATT provisions, but has effected a price control system for pharmaceuticals in order to keep medicines affordable.⁴⁰⁷ While this idea is consistent with the TRIPs agreement and is backed by the WHO, the European Commission and MSF, many developed countries are hesitant.⁴⁰⁸ They fear that the low priced drugs will be re-imported to the industrialized world and consumers in developed countries will not want to pay the higher prices of pharmaceuticals when low prices are offered elsewhere.⁴⁰⁹ In consideration of this fact, proposals to include price control mechanisms will likely be rejected by industrialized countries.⁴¹⁰

F. *Compile a Database of Generic Products*

In May of 2000, Brazil provided a proposal to world health authorities that would benefit developing countries.⁴¹¹ The proposal asked that a database of prices for all AIDS drugs be compiled to allow poor countries to shop around for the best prices worldwide.⁴¹² Generic drugs made in countries like Brazil, Thailand and India would be included in the database allowing countries the right to choose which drugs to acquire.⁴¹³ This would provide poor countries, who do not have the money, technol-

406. See Mike Moore, WTO Director General, *Yes, Drugs for the Poor—and Patents as Well*, *supra* note 223. See also Weissman, *supra* note 10, at 1074 (stating that price controls are common in many industrialized countries and thus should be a viable option). See, e.g., Wechkin, *supra* note 38, at 238. New Zealand is an example of a country that effected pharmaceutical patents but masked the increases in drug prices by instituting a pharmaceutical price support system. *Id.* This system provides the potential to shift the issue from protection of intellectual property to ensuring price regulation allowing the government to control the price and availability of pharmaceuticals. *Id.* However, this solution may not be ideal because price controls, which may work for a developed nation like New Zealand, may restrain the importation of patented technologies into the developing country. *Id.* Without an adequate return on investment, companies will not transfer their latest technology to a developing country. *Id.*

407. See generally Wechkin, *supra* note 38 (advancing the New Zealand price regulation system as a model for other countries including the United States).

408. See Mike Moore, WTO Director General, *Yes, Drugs for the Poor—and Patents as Well*, *supra* note 223.

409. *Id.*

410. Cf. McCabe, *supra* note 9, at 60 (discussing the difficulty of determining what is a reasonable price); Weissman, *supra* note 10, at 1115 (expressing the pharmaceutical industries disdain for price controls).

411. McNeil Jr., *supra* note 396, at A5; *Brazil's AIDS Drug Proposal*, THE PROVINCE JOURNAL-BULLETIN, June 21, 2000, at A11.

412. McNeil Jr., *supra* note 396, at A5; *Brazil's AIDS Drug Proposal*, *supra* note 411, at A11.

413. See McNeil Jr., *supra* note 396, at A5; *Brazil's AIDS Drug Proposal*, *supra* note 411, at A11.

ogy or infrastructure to develop their own generic versions of drugs, access to affordable medicines.⁴¹⁴ This proposal should be adopted for all essential medicines and made available to all developing countries. Countries should be able to shop around for the best price.⁴¹⁵

While the large pharmaceutical companies feel that such a database would encourage countries to disregard drug patents,⁴¹⁶ ensuring access to essential medicines should be a priority for all countries. The major American and European pharmaceutical manufacturers argue against such a proposal and assert that only patent holders should have the right to manufacture and sell the drugs they created, to recover R&D costs.⁴¹⁷ They assert that if patents are protected they will offer discounted prices to developing countries, as was done in early May, 2000.⁴¹⁸ This disregards the fact that even the lower prices offered are still more expensive than generic prices and the conditions attached to the lower prices could not be reasonably met by many developing countries.⁴¹⁹

Further, the large pharmaceutical manufactures assert that such a database would not ensure the safety of all the drugs listed and that the WHO does not have the money to test them.⁴²⁰ However, if the developed world, the WHO and the United Nations work together, testing the quality of drugs provided on the list could ensure their safety. Additionally, providing a price list, does not necessarily guarantee that a country would take the cheapest option, and countries could list on the database whether a drug had met certain safety standards as established by the WHO. Such a remedy is necessary in the face of the serious poverty and poor health that many developing countries face. The violation of patents should not be a concern when people's health is in question.⁴²¹ The WHO must be made to facilitate such programs.⁴²²

In the early 1980s UNICEF began a campaign to vaccinate the world's children.⁴²³ Today, UNICEF's global vaccination system has an 80% success rate saving millions of lives each year and preventing debilitating

414. See McNeil Jr., *supra* note 396, at A5.

415. See *id.* (noting that MSF and ACT UP activists strongly support the Brazilian initiative); *Brazil's AIDS Drug Proposal*, *supra* note 411, at A11.

416. See McNeil Jr., *supra* note 396, at A5; *Brazil's AIDS Drug Proposal*, *supra* note 411, at A11.

417. See McNeil Jr., *supra* note 396, at A5; *Brazil's AIDS Drug Proposal*, *supra* note 411, at A11.

418. See McNeil Jr., *supra* note 396, at A5; *Brazil's AIDS Drug Proposal*, *supra* note 411, at A11.

419. See *Brazil's AIDS Drug Proposal*, *supra* note 411, at A11.

420. See McNeil Jr., *supra* note 396, at A5.

421. *Brazil's AIDS Drug Proposal*, *supra* note 411, at A11.

422. See Rosenberg, *supra* note 219.

423. See *id.*

diseases.⁴²⁴ If the WHO could adopt a system like UNICEF and provide lists of reliable generic suppliers, access to essential medicines would greatly increase for the world's poor. Such a program would likely impose a higher cost on the developed world but the lives that would be saved should outweigh that price.

VII. CONCLUSION

In its 1999 World Health Report, the WHO recognized that reducing the burden of disease suffered by the poor is not just a burden that governments must face.⁴²⁵ The Director General, Dr. Gro Harlem Brundtland, noted that to make real inroads into resolving poverty requires the collective resources and energy of civil society and the private sector in addition to assistance from governments.⁴²⁶ Access to affordable medicines should be a priority for the government of any country, particularly when the issue is the price of a medicine versus the price of a human life.⁴²⁷ The intangible rights of intellectual property pale in comparison to the need to provide access to essential medicines in developing countries. This is particularly the case in light of the spread of infectious diseases, and also the increase in non-communicable diseases. The health gap that exists between developed and developing countries will only continue to escalate if patent protection of pharmaceuticals is an absolute. To reject the truth of this view would be to subject developing nations to the whim of industrialized nations.

Attempting to enforce intellectual property in the area of pharmaceutical patents, as it currently exists, would perpetuate a regeneration of colonialist politics in which the industrialized countries control the economic future of the developing nations by allocating technology and extracting exorbitant royalties in return. Additionally, developed nations and multilateral institutions have an obligation to aid the development of poorer countries rather than retard their growth through restrictive intellectual property policies.⁴²⁸ The health gap is increasingly widening, as evidenced by the difference in death rates and life expectancy between rich and poor countries.⁴²⁹ This review of India is merely one example of a

424. *Id.*

425. WORLD HEALTH REPORT 1999, *supra* note 19, at x.

426. *Id.*

427. *See* Boseley, *supra* note 147.

428. WHA 52.23, *Strengthening Health*, *supra* note 22 (requesting that developed countries, the international community and multilateral institutions should consider the health needs in developing countries and "maintain a people-centered focus in their deliberations, particularly where such deliberations could impact negatively on the health status of the most vulnerable").

429. *See* WORLD HEALTH REPORT 2000, *supra* note 359, at xii.

developing country fighting for the welfare of its people. Prohibiting access to essential medicines affects all developing countries, and providing exceptions for countries on a case by case basis, such as was the case with South Africa, is not a sufficient resolution. The exception provided for South Africa, in the wake of grand scale media attention, should be applied to all developing countries.

The World Health Assembly has reiterated that a country has the sovereign right to adopt national policies specific to the needs of its people.⁴³⁰ The governments of the world must come together to see that the benefits accrued to inventors from patent protection of pharmaceuticals is insignificant to the specific need of protecting life. The benefits for some should not impose suffering on others. Unfortunately, without a significant change in the way the industrialized world enforces patent protection of pharmaceuticals, people in the developing countries will continue to face suffering and an innumerable amount of deaths. This suffering and death can be greatly reduced. The world, this time led by the industrialized nations, must choose to make a difference.

*We can make a difference. Those of us who commit our lives to improving health can help to make sure that hope will predominate over uncertainty in the century to come. Human health - and its influence on every aspect of life - is central to the larger picture.*⁴³¹

430. WHA 52.23, *Strengthening Health*, *supra* note 22.

431. WORLD HEALTH REPORT 1999, *supra* note 19, at vii (emphasis added).